Affordable Medications for Americans (AMA)

Problem, Causes, and Solutions

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SUMMARY

INTRODUCTION

By all reasonable international standards, current spending on prescription drugs in the United States is enough to buy all the medications that Americans need. But today's high spending does not suffice, owing to high prices and inadequate coverage. Our nation and its people therefore face three choices:

- more people suffering and dying for lack of needed drugs—but that is unacceptable;
- spending more to give more people better drug coverage—but that is unaffordable;
- securing more drugs from manufacturers for dollars we already spend.

This report offers strategies for securing access to vital drugs without higher cost.

First, we need **relief**, gaining lower prices and greater volumes of medications so that today's dollars buy the drugs we now need. This will win time to design and test **reforms** in drug development, pricing, prescribing, and use, to make all effective drugs durably affordable for the future.

PROBLEM: MANY AMERICANS CANNOT AFFORD NEEDED MEDICATIONS

Lack of coverage

• Roughly 70 million Americans of all ages—about 1 in 4—have no prescription drug coverage, the Access and Affordability Monitoring Project (AAMP) estimates. This number rises as drug prices rise. Under-insurance for medications is also rising.

High spending

- U.S. retail prescription drug spending is predicted to rise to \$103 billion in 1999 and \$143 billion by 2002. Total prescription drug costs will be about \$120 billion this year.
- Retail prescription drugs will consume 8.4% of U.S. health spending in 1999, up from 7.2% in 1997. Total prescription drug costs will be 9.8% of health spending.
- Per person U.S. prescription drug spending is now about \$377 retail and \$425 total.
 At prevailing rates of increase, prescription drug spending per person in the U.S. will be the world's highest either this year or very soon.
- Prescription drug costs are rising about three times as fast as overall health costs.

High prices

- For decades, the world's prescription drug makers have charged Americans more for the same pills (often from the same factory) than they charge in any other country.
- Yet we buy 1/3 of the world's prescription drugs, which should let us win low prices.

- In the early 1990s, drug makers charged Americans 32% more than Canadians for the same drugs. That gap suggests **Americans would save roughly \$16.2 billion yearly if we paid the wholesale prices paid by Canadians**. By at least that sum, we subsidize other wealthy nations who do not pay their fair share of drug costs.
- Recently, U.S. prices rose as Canada's prices fell. Other wealthy nations have long paid even less. So the international cost-shift onto Americans is probably growing.
- Even the \$16.2 billion minimum estimate of the U.S. drug subsidy to wealthy nations is more than double the \$7.6 billion in bilateral foreign aid appropriated by Congress in 1999 to aid vulnerable or starving nations.
- The drug industry contradicts itself, saying that price controls abroad both work and don't work, denouncing controls as ineffective but also as constraining their revenue.
- And U.S. drug prices are rising again—2.4 times as fast as the overall Consumer Price Index (April 1998-99), and at an annual rate of 6.1% in early 1999.
- Because discounts for some Americans now mean a **domestic cost-shift** to others, people who lack coverage—many poor, sick citizens—pay the highest prices of all.

CAUSES: WHY ARE SO MANY PEOPLE UNABLE TO AFFORD NEEDED MEDICATIONS?

Government inaction

- U.S. prescription drug prices are high mainly because our government fails to protect us against drug companies as other governments protect their citizens.
- Drug makers' acceptance of price and profit caps in other nations is surely greater because they can freely raise prices for Americans, the world's shock absorber.

Research?

- Since all drug manufacturers charge more in the U.S. and appear to earn a disproportionate share of their profits here, how can American drug makers claim that high profits enable them, uniquely, to conduct more breakthrough research?
- Pharmaceutical research in the U.S. was 0.97% of health spending in 1990-94, but averaged 1.53% for the U.K., Japan, France, Italy, Germany, and Canada.
- Globalization makes it hard to judge industry attribution of research to single nations.
- Better drugs may cut short-run health costs, but long-run savings are far from sure.
 And we must not revere potential future cures while we deny people existing cures.

Profits

- In 1998, pharmaceuticals were **the most profitable industry** in return on equity, on revenue, and on assets. Remarkably, return on equity reached 39.4 percent in 1998.
- Indeed, drug makers had strikingly high profits for 7 decades, from the 1930s to '90s.
- Drug making was the most durably profitable U.S. industry over the past 3 decades.
 Its median return on equity was 1.5 times the all-industry average in the 1970s and '80s, improving to 2.3 times the average in the 1990s.

- The high drug industry profits year after year raise the question: Where is the risk?
- Drug companies must be asked to specify and negotiate the profit level they
 need to attract and retain sufficient capital to operate successfully in the public
 interest by developing and producing innovative, effective, safe and affordable drugs.
- Large drug companies rely on others to do much of the riskiest, early-stage research. Public funding for bio-medical research appears far greater in the U.S. than abroad.
- Profits exceed research costs at the top 10 U.S. drug firms, Public Citizen found. Merck and Pfizer used an average of only 11% of revenue for R&D in 1997, with 29% of revenue for marketing and administration and 19% for profit, the AAMP finds.

Lack of competition

- Patents grant monopolies to drug makers to spur innovation. But that gives drug
 makers much power over prices. Other nations offset this pricing power with
 government action to make drugs affordable and achieve free-market price levels.
- Laws that bar parallel imports and limit access to generics also reduce competition.

Manufacturers' pricing strategies

• Diverse evidence makes clear that drug prices are not set in direct relation to R&D costs. So it is wrong to claim that high prices are required to finance drug research.

Income inequality

- The **domestic cost shift** means drug makers and retailers extract higher prices from Americans who pay out-of-pocket. Yet these Americans disproportionately suffer low incomes. It is hard to imagine a less just arrangement.
- The problem is magnified since U.S. incomes are the industrial world's least equal.

Underlying reasons for the failure to make needed prescription drugs affordable

- These include governments' small role in paying for drugs; payors' focus on costshifting; drug makers' political power and campaign contributions; and focus on steps that cannot yield adequate savings (such as using generics and squeezing retailers).
- Drug makers and the Pharmaceutical Research and Manufacturers of America (PhRMA) say that if Americans do not pay high prices to "bear the world's research burden," many new drugs will not be developed. But:
 - Lower U.S. prices need not mean lower revenue and profit for drug makers if they cut costs, boost volume, or raise prices in other wealthy nations. (Charging poor nations more gains nothing, as they generally cannot pay more.)
 - Drug makers all face the same pricing policies worldwide. A more plausible engine of U.S. innovation is public funding for biomedical research through NIH.
 - We need not choose between extraordinary profits and high research spending on one hand and no profits and no research on the other. PhRMA ignores reasonable middle grounds, as the drug makers' first duty is to stockholders.
- The world's drug makers use market rhetoric but harvest huge profits from the U.S. because there is no free market for prescription drugs, either here or internationally.

• With neither a functioning free market or effective government intervention, anarchy ensues. Those with power—drug makers with monopoly or oligopoly power—can raise prices and profits above free market levels. This better explains high drug industry profits than do claims of risky investment or innovative research.

WHAT PRIVATE, FEDERAL, AND STATE SOLUTIONS ARE POSSIBLE?

Recommended solutions

- U.S. policy on prescription drug financing should aim to:
 - assure that all Americans can afford needed prescription drugs,
 - do so without increasing public or private spending, and
 - maintain adequate profits so that the industry can develop new drugs.
- Plans to discount prices for groups of patients would make drugs more affordable, while other plans would use rebates to secure more drugs without spending more.

Inventory and assessment of possible solutions

- This report briefly analyzes 19 public and private methods of winning lower drug prices and 7 public and private methods of winning better drug coverage.
- Massachusetts, Vermont, and other states are considering pooling statewide buying power to negotiate discounts with drug makers. The plan would make drugs more affordable to all, end the domestic cost-shift, and reduce the international cost-shift. Higher sales would offset some revenue loss for drug makers.
- AAMP uses estimates that 10% **lower drug prices would raise demand** 3.3%, thus offsetting some revenue loss for drug makers. Merrill Lynch projects more rise in demand, suggesting that a 40% discount for Medicare patients (as in Rep. Allen's bill, H.R. 664) would yield from a 3% drop to a small rise in drug maker revenue.
- Under the just-noted Massachusetts and Vermont bills, the states would negotiate
 with drug makers to win rebates as well, to help expand drug coverage. Most of the
 rebated sums would return to the drug makers to buy more pills. Marginal costs of
 making more pills are very low (estimated at 5% of the retail price). So such rebates
 would cost manufacturers surprisingly little.
- Such discounts and rebates combined would mean an estimated gain to patients at least twice as great as the proposals' cost to drug makers.
- Alternatively, the federal or state governments could negotiate with drug makers for in-kind donations. Companies could offer credit equal to perhaps 25% of their sales in a jurisdiction; costs of drugs for patients in need would be debited against the letter of credit. Dispensing costs could be paid by patients, public funds, or drug makers.
- Providing 25% more medications in the U.S. would cost the world's drug companies only about \$1.25 billion. If the 12 largest U.S. drug makers had borne this entire burden in 1998, their combined profits would have fallen by \$1.25 billion—the cost of making the added drugs—leaving them securely in 1st place among U.S. industries. Americans would have gained additional medications with a retail price of \$25 billion—without higher taxes, premiums, or out-of-pocket costs.

- The cost of making more drugs need not erode industry profits at all. Drug makers can cut waste, especially in advertising, public relations, lobbying, and executive pay. (In 1997, 10 drug company CEOs alone received \$229 million.) And drug makers, with U.S. government help, should act to end today's international cost shift.
- Simple government action can cut drug prices, making needed drugs available for all Americans without great public cost and at little cost to drug makers.

Elements of durable reform

- Steps are also needed to assure better use of prescription drugs and make them durably affordable. Durable reform requires:
 - (1) **negotiating an international treaty that cuts U.S. drug prices** and gets other wealthy nations to start paying their fair share of drug research costs and profits;
 - (2) assuring fair and adequate returns on invested equity;
 - (3) better evidence on each existing drug's benefits and costs, so physicians can prescribe more reasonably;
 - (4) better education for physicians, financed and disseminated by objective parties;
 - (5) better patient education about proper drug use; and
 - (6) targeting research to develop medications that are affordable and effective.
- Fair levels of profit should be negotiated between payors and manufacturers—levels adequate to retain and attract the capital to finance necessary research.
- The broad outlines of fair international drug pricing are clear:
 - Wealthy nations all should pay the same prices for drugs, to finance most of drug makers' legitimate research, manufacturing, and other costs.
 - Moderate-income nations should pay prices that cover the incremental costs of the medications they use, plus a small contribution toward fixed costs.
 - Poor nations should obtain needed drugs at no more than symbolic prices.
- Now is the time to begin changing course. Throwing more money into business as usual will make it harder to cure drug companies of their addiction to high prices.

CONCLUSIONS

- Prices must fall so that Americans pay only our fair share of the cost of profits and drug research. In exchange for the large sums we spend on medications, all drug makers must agree to provide needed volumes of drugs to all Americans.
- Winning affordable and effective medications for all Americans requires both federal
 and state efforts. State-level action could be effective in part because states have
 surprising purchasing power: California's health spending is greater than
 France's, for example, and health spending in Texas exceeds Canada's.
- The future trajectory of prescription drug policy and financing should be planned cooperatively among all stakeholders.
- Since U.S. prescription drug spending per person will soon be the world's highest, winning affordable drugs for all should be the easiest job facing our nation.

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A. INTRODUCTION

Current spending is already enough to buy all the prescription drugs that work for all the Americans who need them. Yet most proposals to address the problem of prescription drug affordability fall far short of that goal. Although some observers may say that goal is unrealistic, the reverse is true. It is the alternatives that are unrealistic. Further suffering is unacceptable, and higher spending is unaffordable.

Two predictable crises. Too many Americans are unable to afford their prescription drugs because they lack purchasing power and because prices are too high. **Some 70 million Americans—one-quarter of us—lack insurance coverage for prescription drugs**. These numbers can be expected to increase in the face of higher prices for existing drugs, development of new and costlier drugs, and employer or insuror decisions to drop prescription drug coverage. And many people who do have insurance have meager coverage.

High prices make it much harder for people without insurance coverage to afford needed prescription drugs. Americans already pay the world's highest prices for prescription drugs and drugs are already the fastest-growing component of health costs.

Indeed, retail prescription drug spending in the United States grew by 42.9 percent during the three years from 1994 to 1997, almost triple the overall rise in U.S. health spending of 15.3 percent.^{1,2} (Please refer to Exhibit 1, titled "Total Health and Prescription Drug Spending, U.S., as Percent of 1994 Spending," on the following page.)

Spending on drugs will probably accelerate. Many drugs now under development promise to be very effective but threaten to be very costly. To win higher revenues, drug manufacturers heavily advertise and market. By industry predictions, U.S. prescription drug spending would rise by an additional 43 percent from roughly \$100 billion in 1998 to \$143 billion in 2002.³

By all reasonable international standards, this should be enough money to buy all the medications that Americans need. That, in turn, should make the job of getting affordable prescription drugs to all Americans the easiest problem to solve in the United States.

Three choices. In the face of these growing problems, our nation and its people have three choices:

- Many of us could suffer and die for lack of needed and effective medications.
- We could spend more money on prescription drugs to provide better coverage for more people.
- We could secure more drugs from manufacturers for the amount we already spend.

The first choice is unacceptable. The second choice is, at best, a temporary stop-gap. When a person is bleeding, first aid is needed. But drug costs are rising so fast that much more than first aid will be needed in only a few years. Without reasonable changes in how we finance

prescription drugs, higher spending today will have to be followed by still higher spending tomorrow.

That leaves the third choice. This nation's current level of spending on prescription drugs should be adequate to finance all the medications needed today.

We must get our house in order before we are hit by the storms of rising numbers of people without insurance for prescription drugs and rising spending on costly new drugs. First, we need relief. This means making sure that all Americans can afford today's drugs when needed. Second, we can begin designing and testing ways to reform our methods of developing, pricing, prescribing, and using medications.

Relief and reform. This brief report begins by describing the two problems that many people face in affording needed prescription drugs—high prices and inability to pay those prices owing to lack of insurance or low income. After describing the causes of the problem, it describes and briefly analyzes possible solutions that attack these causes. In doing so, it focuses on the problem of relief—of making today's medications affordable to all Americans who need them.

It will be desirable to win lower prices and greater volumes of medications, so that today's dollars indeed buy the medications we now need. Negotiating fair prices for today's medications and financing these medications for all Americans will buy time. That is what is meant by relief in this report. The time bought by this relief should be used to design, test, and put in place more comprehensive reforms.

Steps are needed to assure better use of prescription drugs and make them durably affordable. Durable reform requires:

- (1) **negotiating an international peace treaty that lowers U.S. drug prices** while getting other wealthy nations to start paying their fair share of drug research costs and profits;
- (2) assuring fair and adequate returns on invested equity:
- (3) better evidence on each existing drug's benefits and costs, so physicians can prescribe more reasonably;
- (4) better education for physicians, financed and disseminated by objective parties, not by industry;
- (5) better patient education about proper drug use; and
- (6) more careful targeting of research to develop medications that are affordable and effective.

Now is the time to wrestle seriously with this nation's real prescription drug problems, and to gradually change course in a durably affordable and decent direction. Doing so means winning relief from high prices and lack of coverage today, and designing longer-term reforms for tomorrow. The longer we continue to throw more money into financing business as usual, the harder it will be to cure the drug companies of their addiction to inordinately high prices.

B. THE PROBLEM: MANY AMERICANS CAN'T AFFORD NEEDED MEDICATIONS

Many Americans are not able to afford prescription drugs because they lack insurance or personal financial resources to buy drugs, and because U.S. prices are so high.

1. How Many People Lack Insurance for Medications?

Three groups of people lack insurance for prescription drugs. Some 43.4 million Americans had no health insurance at all in 1997. But many Americans with some insurance also lacked coverage for prescription drugs. In 1995, roughly 12.8 million Medicare beneficiaries—over one-third of those residing outside institutions—had no prescription drug coverage. Additionally, an estimated 7 percent of those with private health insurance do not have prescription drug coverage. The Access and Affordability Monitoring Project (AAMP) estimates their numbers at perhaps 11.6 million in 1997.

These three groups totaled 67.8 million Americans in 1995-1997, and may have risen to *perhaps 70 million people today. That would leave 25.7 percent of all Americans without prescription drug coverage in 1999.* Roughly four-fifths of the people without prescription drug coverage are under age 65; seniors, though, are more likely to need costly medications. (Further, "low-income seniors are less likely to have prescription drug coverage and more likely to forego necessary medications." These numbers and proportions vary from state to state.

Additionally, it appears that substantial numbers of people are under-insured for prescription drugs. Some, for example, have public coverage or private policies that place annual or even quarterly ceilings on spending. These ceilings are adequate for people who do not need costly drugs, but are not adequate when insurance protection is most needed. Under-insurance also afflicts patients who cannot afford the increasing co-payments charged by insurors and HMOs, including the new third tier of co-payments that range up to \$25 or even \$50 per prescription. It seems that both of these forms of under-insurance are growing. In addition, some patients are charged a fixed percentage co-insurance (such as 50 percent) on each prescription. Rising prices on existing medications and the introduction of costly new medications therefore impose high co-insurance expenses on these patients.

2. High Spending

In 1999, retail prescription drug spending in the United States appears likely to total roughly \$103 billion, or about \$377 per person. When in-hospital, nursing home, and other non-retail prescription drug spending is included, the 1999 total rises to roughly \$120.2 billion, or about \$425 per person. 3

U.S. pharmaceutical spending per person reported by OECD was \$319 in 1997.¹⁴ This made it fourth-highest in the world, according to OECD estimates.¹⁵ (See Exhibit 2, "Pharmaceutical Spending per Capita, Wealthy Nations, 1997.") U.S. spending per person was exceeded only in France, Japan, and Belgium.¹⁶

At prevailing rates of increase, U.S. spending per person will soon be highest in the world.¹⁷ Prescription drug spending was the fastest-growing component of U.S. health costs between 1994 and 1997. As was shown in Exhibit 1, it rose roughly three times as fast as

overall health spending.¹⁸ Rapid cost increases are expected to persist. And, as noted earlier, U.S. prescription drug spending is projected to reach \$143 billion by 2002.¹⁹

By all reasonable international standards, this should be enough money to buy all the medications that Americans need. That, in turn, should make the job of getting affordable prescription drugs to all Americans the easiest problem to solve in the United States.

But this spending does not suffice. And that is the problem before us now. This problem has two main aspects: prices and overall spending are high, and many people don't have enough money to pay those prices, either through insurance or out-of-pocket.

3. High Prices

U.S. drug prices are highest in the world²⁰ —even though our huge market share should give us the buying power to win the world's lowest prices, if we wanted that. As shown in Exhibit 3, "The World's Pharmaceutical Market," Americans bought 33.2 percent of the world's drugs in 1996, as measured in manufacturers' revenues, not in use of medications.²¹ And the U.S. share is rising.

Drug prices in the United States have been extraordinarily high for as long as they have been measured and compared. For example, through hearings before and data developed by Sen. Estes Kefauver's Subcommittee on Antitrust and Monopoly between 1959 and 1961, it was found that both American and foreign drug makers charged substantially higher prices in the United States than elsewhere. The six medications considered in this table averaged almost four times as costly in the United States as in other nations:²²

Table
Prices of Six Medications, U.S. and Foreign, 1959-1961

Medication (maker)	U.S. price	Foreign price (nation)	U.S. % of foreign price
Meprobramate (U.S., generic)	\$ 3.25	\$ 1.38 (Germany)	235.5%
Penicillin V (Lilly)	\$18.00	\$ 6.50 (U.K.)	276.9%
Compazine (Smith, Kline)	\$ 3.93	\$ 0.80 (France)	491.2%
Orinase (Hoechst)	\$ 4.17	\$ 1.85 (Germany)	225.4%
Reserpine (CIBA)	\$ 4.50	\$ 1.00 (Europe)	450.0%
Thorazine (Rhone Poulenc)	\$ 3.03	\$ 0.51 (France)	594.1%
Average			378.9%

Source: Estes Kefauver, In a Few Hands: Monopoly Power in America.

High U.S. drug prices have persisted in the decades since Sen. Kefauver noted the problem. Drug manufacturers charge lower prices in other wealthy countries for the same pills—often

made in the same factories. In the early 1990s, for example, drug companies charged Americans wholesale prices 32 percent above those that they accepted for the same drugs in Canada.²³

These price disparities mean that Americans are burdened with enormous excess costs. The amount that our nation would save in 1999 alone if we bought medications at Canadian wholesale prices is roughly \$16.2 billion.

And that is a minimum estimate, using the 1991 gap between manufacturers' prices in the U.S. and Canada. But drug makers have charged even less in many other wealthy nations. Further, U.S. prices for most drugs have risen recently, while prices in Canada and other wealthy nations have been falling—so the international price gap is almost certainly greater today.²⁴ Canadian government analyses have found that, in 1997, for example, prices rose on 62.6 percent of patented drugs in the U.S., but rose on only 20 to 24 percent of patented drugs in five other wealthy industrial nations. (See table.) These data suggest that prices in the U.S. and other such nations have been moving farther apart.

Table Price Changes of Patented Drugs in Seven Countries, 1997

Percent of Patented Drugs With Price Increases in 1997
24.0%
23.4
24.4
40.6
28.7
24.2
20.4
62.6

Source: Canada's Patented Medicine Prices Review Board, Trends in Patented Drug Prices, 1998.

The excess U.S. spending on drugs in 1999 because of our high prices—estimated at a minimum of \$16.2 billion—permits lower spending in other wealthy nations. And the international subsidy, or cost-shift, is far larger if it is assumed that the much lower Swedish, British, or Australian prices might be obtainable here.

The extra cost imposed on Americans is shown in Exhibit 4, "Estimated U.S. Wholesale Prescription Drug Spending Using Prices Paid by Several Nations, \$ Billion, 1999." Those extra costs constitute a subsidy from Americans to people in other wealthy nations.

This should be viewed as an unusual form of foreign aid—albeit a uniquely ill-targeted one—never voted publicly but rather designed and administered privately by the world's prescription

drug manufacturers. *Yet even this \$16.2 billion minimum estimate of the cost of the U.S. subsidy to other wealthy nations is more than double the bilateral foreign aid of \$7.6 billion that Congress actually appropriated in 1999* to aid the citizens of vulnerable or starving nations.²⁶ Exhibit 5, "Foreign Aid: What Congress Votes versus What the Drug Companies Extract, Conservative Estimates, 1999, \$ Billion," displays this comparison.

Today, all the world's drug manufacturers plunder American patients and consumers, forcing us to pay more than our fair share of research and profit costs. The aim of identifying this problem is not to engender anger or selfishness. And it is not to motivate our nation to seek the world's lowest prescription drug prices, something that we might be able to win by using the leverage of our extraordinary buying power. Rather, it is intended to motivate fair international pricing for medications—pricing that sees all wealthy nations paying their fair shares. It is appropriate for all the wealthy nations to subsidize access to prescription drugs for poor nations, but the other wealthy nations do not need subsidies from Americans.

The drug manufacturers face an awkward problem when confronting high U.S. prices. On one hand, they don't want to admit that other nations have won lower prices through government action. So Pharmaceutical Research and Manufacturers of America (PhRMA) usually tries to insist that U.S. prices are not high or are not higher than would be expected in light of high U.S. incomes or other factors. ²⁷ But, on the other hand, the drug manufacturers denounce foreign price controls, price negotiations, or parallel importing provisions ²⁸—claiming that these unwarrantedly deny revenue to the manufacturers.

PhRMA has demonstrably misrepresented U.S. General Accounting Office findings regarding the efficacy of price controls in four European nations. PhRMA has stated that "price /profit controls imposed by France, Germany, Sweden, and the U.K. ... did not work." But the GAO study's authors actually wrote just the opposite, that policies of price and profit controls "appear to have been effective at restraining drug prices, but they have been unable to prevent continued increases in drug spending." And why did overall drug spending continue to increase? Because of "two factors—higher pharmaceutical consumption and the use of newer, more expensive drugs. Government policies have not controlled these forces entirely, but they have likely kept drug spending from rising even more rapidly." In other words, government price and profit controls worked to hold down prices but still allowed greater use of medications and introduction of new and more costly drugs.

The drug manufacturers' own claims that free market forces have worked to hold down prices have been undermined by new reports of substantial price increases.³¹

To try to explain the rapid increase in total spending on prescription drugs in the U.S., the drug manufacturers highlight introduction of new medications and rising rates of use for existing medications. They downplay the role of price increases, claiming—for example—that higher prices accounted for only 3.2 percentage points (or about one-fifth) of 1998's overall 15.7 percentage point rise in total U.S. prescription drug sales. Indeed, in 1995, the prescription drug component of the consumer price index (CPI) rose more slowly than the overall CPI for the first time in a great many years. More recently, though, *price increases have again been a growing problem. From April of 1998 through April of 1999, prescription drug prices rose at a rate 2.4 times as great as the overall CPI.*³³ And during the first five months of 1999, drug prices rose by an annual rate of 6.1 percent.³⁴

PhRMA opposes state or federal government actions to win lower prescription drug prices for Americans. But if its claims that government actions abroad had failed to achieve lower prices were true, why would it bother to oppose similar efforts here in the United States?

The drug industry may finance studies by economists or others that purport to show that U.S. drug prices are not the highest among the world's wealthiest nations. But American patients visibly travel to Canada to buy drugs, and have done so for a number of years; no reverse flow has been detected.³⁵ (And at least in the early 1990s, Canadian drug prices were second highest in the world, after those in our own nation.³⁶) Such direct evidence should command the attention of all, whatever their prior views.

In at least four ways, PhRMA has described how specific foreign nations' actions have won lower prices for their citizens:

- PhRMA has written that many nations, "including the major industrialized countries of Europe, distort the market by imposing price controls on drugs...." And then, PhRMA has explicitly conceded that this has been "causing `cost shifting' to free market countries such as the U.S." This is an admission that U.S. prices are higher—and that they subsidize the lower prices elsewhere.
- PhRMA's solution to the problem of cost-shifting is to demand that all countries "abandon price regulation." Since foreign governments are not going to do that, PhRMA's strategy effectively would consign American patients to paying higher prices.³⁸
- Similarly, as discussed later, PhRMA asserts that U.S. consumers had no choice but to "bear the world's research burden." Here, too, PhRMA acknowledges that U.S. prices were higher than—and subsidized—those in other wealthy nations.³⁹
- PhRMA acknowledges that other nations control domestic drug prices, so their domestic drug manufacturing industries remain innovative [and profitable] by selling their products abroad ⁴⁰—especially to the United States.

This analysis has not attempted to quantify the balance-of-trade problems associated with the international imbalance in prices for prescription drugs. Factories in the U.S. sell abroad at prices constrained by foreign governments. Factories located abroad sell in the U.S. at prices unconstrained by government. Although prescription drug sales show a moderate trade balance in favor of the United States,⁴¹ that balance could be substantially greater if prices were equalized among wealthy nations.

Owing to higher prices, higher use rates, and the introduction of costly new drugs, spending on drugs is rising in the U.S. as a share of the health dollar. As shown in Exhibit 6, "Retail Prescription Drugs as Percent of U.S. Health Spending, 1960 – 1997," retail prescription drugs consumed 10 percent of the nation's health dollar in 1960. The share bottomed out at 4.7 percent in the early 1980s, rose gradually until 1995, but then jumped sharply in 1996 and again in 1997, to reach 7.2 percent. By 1999, the AAMP estimates, the retail drug share of U.S. health spending has probably risen to 8.4 percent, or one in every 12 health care dollars. It is reasonable to anticipate a substantial rise in this share in the years ahead if today's forecasts are fulfilled.

And Americans also pay for prescription drugs in non-retail settings such as in hospitals and nursing homes. If, as estimated earlier, total prescription drug spending nationally in 1999 is \$120 billion, that amounts to nearly one-tenth (9.8 percent) of the nation's total health expenditures of \$1,229 billion. 45

Exhibit 7, "Prescription Drug Spending as a Share of Gross Domestic Product" shows that prescription drugs' share of U.S. gross domestic product is below that prevailing in other wealthy nations. This is because we spend so much more on hospitals and doctors than others do, because our per capita gross domestic product is higher, and because U.S. rates of use of prescription drugs are apparently below the average for other wealthy nations.

But the relatively low percentage of health dollars or of GDP devoted to prescription drugs is a red herring. What matters is the money spent per person on medications. And here as noted earlier, the U.S. will soon be number one, if it is not already.

Just as U.S. prices are higher than those in any other nation, so prices within the U.S. are particularly high for people without insurance. These domestic price disparities arise because of a domestic cost-shift. After Medicaid, the Veterans Administration, the managed care plans and big insurors, hospitals, and other parties with some bargaining power win their discounts, manufacturers and retailers raise prices for the people without bargaining power—people without insurance and therefore without anyone to negotiate for them. It is particularly unjust that our poorest patients—and many of our sickest patients—are burdened with the world's highest prices.⁴⁷

Increasing realization of this domestic cost shift has probably helped to inspire proposed state and federal legislation that would give seniors and others access to lower prices already won by parties with bargaining power. These proposals are discussed in section D of this report.

C. WHY ARE SO MANY PEOPLE UNABLE TO AFFORD NEEDED MEDICATIONS?

1. Causes of High Prices

<u>a. Government inaction.</u> Prescription drug prices in the United States are high mainly because, unlike other nations, our government fails to protect us from drug companies. A considerable amount of evidence demonstrates that governments in other nations set drug prices, negotiate them down, set budgeted spending ceilings, cap profits earned on domestic sales, or take similar steps to lower effective prices and spending.⁴⁸

The drug companies often accept those constraints with little resistance.⁴⁹ It is reasonable to suppose that the manufacturers' willingness to accept restraints on their revenues in other nations is increased by their ability to raise prices on hapless Americans, the world's shock absorber. The manufacturers fight government action in the United States by claiming that:

- such action would imperil needed research;
- current profit margins are legitimate—as well as simply trying to deny that U.S. prices are high; and
- · market forces will lead to lower prices.

<u>b.</u> Research? The drug manufacturers insist that high U.S. prices are justified by the volume of research performed by U.S. manufacturers, by the high costs of research, by the high percentage of drugs that are never profitable, and by the benefits to health and the savings in hospital and physician costs won by using new and effective prescription drugs.⁵⁰

But these claimed justifications are without merit for three reasons. First, the claims themselves are untrue in important ways.

- As shown earlier, all the industrial world's drug makers charge higher prices in the United States, and therefore seem to earn a disproportionate share of their profits here. How, then, could American manufacturers claim that high profits enable them—uniquely—to conduct more breakthrough research?
- U.S. drug manufacturers do perform large amounts of research, but the financial burden of this effort is anything but extraordinary. Pharmaceutical research in the U.S. was only 0.97 percent of health spending in 1990 1994, compared to an average of 1.53 percent for the U.K., Japan, France, Italy, Germany, and Canada.⁵¹ (See Exhibit 8.)
- A similar result appears in using the industry's own data on drug manufacturer-financed research in 1995. The AAMP finds that U.S. firms' share of the industry's research in eight leading nations is simply proportional to this country's share of the same eight nations' population— and, again, far smaller than the U.S. share of health spending. 52
- A great deal of research is performed, and much of it does not bear fruit. But how much of that research is relatively low-risk research, performed to develop the so-called copycat or me-too drugs that do relatively little to enhance well-being? And how much of what is called research is really market research, rather than clinical research? Schondelmeyer asserts that American drug makers do not develop greater numbers of breakthrough drugs—new molecular entities—than do Europeans, in proportion to research investments.⁵³

• Developing and using more drugs and more effective drugs as a substitute for surgery or for hospital care would probably do a great deal to enhance our well-being. Spending more money on drugs might save money overall, as some hope or claim,⁵⁴ but it might not. Imagine an effective medication that prevented the formation of plaque in coronary arteries and thereby prevented many heart attacks. That would be a blessing for humanity. It would probably reduce the cost of medical care in the short run. But it is far from clear that money would be saved in the long run.⁵⁵

And even if higher spending on drugs were to save money on hospitals or doctors, this does not rationalize either paying higher prices than necessary to finance that research, or rewarding manufacturers with unearned profits.

The U.K., France, Germany, and Sweden were the subject of a U.S. General Accounting
Office study of prescription spending control policies, which in all four countries focus on
manufacturers' prices. Noting that more than one quarter of new drug entities from 1970 to
1992 were developed by firms based in these four countries, the GAO concluded that

...the presence of pharmaceutical regulation does not preclude the existence of an innovative industry [H]igher drug prices contribute to the development of new drugs by encouraging firms to devote more resources to R&D. However,.... drug prices are only one of many factors that influence pharmaceutical R&D. Therefore, pharmaceutical spending control policies can coexist with a strong research-based industry, even though by themselves such policies would decrease R&D spending. ⁵⁶

In Switzerland, all drug makers must negotiate prices with the government before selling a drug at all, even outside of public insurance plans. Switzerland has set the price of each new product in relation to the price of a similar product in other countries. Yet Switzerland is home of several of the world's major drug companies.⁵⁷

Conversely, high prescription drug prices are no guarantee of strong R&D efforts, the GAO observed, noting that Canada and several other countries with relatively high drug prices had relatively little pharmaceutical industry research.⁵⁸

- Industry claims about the power of U.S. research are increasingly difficult even to discuss, given the growing globalization of pharmaceutical companies. PhRMA makes assertions that rest on categorizing breakthrough drugs by nationality, but it is unclear how those categories are determined. What is PhRMA's standard? (Obstacles to making such attribution of research to individual nations may include these: a given drug maker may have employees in several nations; work can be shared across national boundaries; and patents may be sought first where they are easiest to obtain or where there appear to be market advantages, rather than where the work was done.)
- Perhaps most important, it is wrong to revere research on potential future cures while sacrificing Americans who cannot afford existing cures. PhRMA claims that profits are necessary to innovation, and that high U.S. prices are necessary to profits. The implication is clear: Americans must sacrifice today to win a better future. But the sorts of people who are martyred to high drug costs today—people without insurance or savings to afford expensive medications—are exactly the sorts of people who will also suffer in the future. Worse, still higher prices for new drugs will leave still more Americans unable to afford tomorrow's remedies.

Second, were U.S. manufacturers' claims that they perform disproportionate amounts of research valid, this would still not in any way justify higher prices in the United States. It might justify higher drug prices internationally, but that is entirely a separate matter. Shouldn't all nations using those drugs pay their fair shares of the cost of their development?

Third, manufacturers do not set prices to cover research costs. They set prices as high as they can, in hopes of maximizing revenue. When they face little pressure from competing manufacturers, as when they enjoy a monopoly or an oligopoly, they are able to set very high prices.⁵⁹

c. Profits. The drug companies' desire to earn high profits also helps to explain high prices. In 1998, pharmaceuticals were the most profitable industry. This held when profitability was measured by return on equity, return on revenue, or return on assets. Return on equity reached 39.4 percent in 1998, a remarkable level. 60

Extraordinarily high drug company profits are not a recent or episodic phenomenon. The drug industry has been found to enjoy unusually high profits over the seven decades from the early 1930s through the late 1990s.⁶¹

Sen. Kefauver's subcommittee, which investigated the drug industry between 1959 and 1961, reported that the drug industry was the most profitable in the United States and averaged double the return on equity of all manufacturing industries from 1957 through the early 1960s. Sen. Kefauver's subcommittee also reported very high profits for two drug firms in the 1930s as well. Sequence of the control of the con

The AAMP has compiled data on drug industry profits between 1970 and 1998. As displayed in the text table, below, U.S. drug industry median returns on stockholder equity averaged 21.5 percent annually between 1970 and 1998 according to *Fortune* 500 reports.⁶⁴ Prescription drug makers' median profits have averaged three-quarters higher than the median for all industries of 12.6 percent between 1970 and 1998.

Further, average profitability rose over the three decades, from 15.0 percent in the 1970s to 20.6 percent in the 1980s, and to 29.7 percent in the 1990s. For ten of the 25 years for which data are available, the pharmaceutical industry ranked first; this was true for seven of the nine years for which data are available from 1988 through 1998. Drug companies' ranking on median return on equity averaged 2.2 between 1970 and 1998; this improved to an average of 1.4 between 1990 and 1998.

Compared with other industries, the median return on equity in pharmaceuticals was one and one-half times the average of all industries in the 1970s and 1980s, improving to two and one-quarter times the average in the 1990s. Exhibit 9 compares median return on equity of the pharmaceutical industry with the median across all industries from 1970 through 1998. Then, Exhibit 10 displays the ratio between the two rates of return for the same years.

Table

Pharmaceutical Industry Profitability,

1970 – 1998

Median return on equity	<u>1970-98</u>	<u>1970-79</u>	<u>1980-89</u>	<u>1990-98</u>
Pharmaceutical industryAll U.S. industries	21.5% 12.6%	15.0% 11.3%	20.6% 13.7%	29.7% 13.3%
Pharmaceutical % of all	176.4%	149.7%	151.4%	228.2%
Pharmaceutical industry average rank among industries (return on equity)	2.2	2.4	2.6	1.4

Note: The final row in the table, labeled Pharmaceutical industry average rank among industries (return on equity) indicates the industry's ranking among all industries in the *Fortune* 500. For example, from 1970 to 1998, the drug industry ranked an average of 2.2. The 2.2 is the average ranking over these years, or about second-best among all industries. From 1990 to 1998, the ranking of 1.4 indicates an average ranking of between first and second—a little closer to first-best.

Further, a sample of large and small drug companies ranked first in return on equity among 87 industries from 1969 through 1989, according to a study commissioned by the *Philadelphia Inquirer*. At least during this period, then, high profits have not been limited to the largest firms, the 1,000 analyzed by *Fortune* in recent years.

These data indicate that the pharmaceutical industry has maintained an extraordinarily high level of profitability—and one that generally trends upward—over three decades. Returns on equity during the past five years have been the highest reported for the industry.

The drug industry was more than twice as profitable as the all-industry median in 1970 and 1971, perhaps owing to losses in other industries from inflation associated with the Viet-Nam war. Then, for the fourteen years through 1985, drug industry median profits averaged only 28.3 percent more profitable than the all-industry average. But from 1986 on, drug profits averaged 211.2 percent as profitable as the all-industry average—or more than twice as profitable.

During the 1990s, for example, drug industry profitability improved substantially, whether compared to drug industry profits during past decades, or to all-industry median profitability during the 1990s. This happened despite any possible demands for discounts, rebates, or changes in patterns of drug use by managed care organizations, federal agencies, Medicaid programs, or others.

Possible reasons for this spectacular and sustained improvement in profitability include: price increases on existing drugs, marketing new drugs at high prices, increase in sales of drugs with low marginal costs, improved tax treatment, and moving manufacturing to lower-cost locations. Speedier FDA approval of new drugs might be a factor, but the increase in profitability antedated the acceleration in approval. But all this is speculation. Although analysis of the causes of the rise in profit is beyond the scope of this report, the implication of that rise is clear: there is room to lower prices (or to provide higher volumes of medications without raising total revenue) while providing profits at margins that were long considered very substantial.

The drug companies persist in denouncing any potential constraint on their U.S. revenues or profits. ⁶⁶ They insist, in practice, that they need all the money they can extract from Americans in order to finance vital research. But they must be asked: How much profit do they really require? What is the minimum profit they need to finance vital research? And what is their upper limit on their profits, if any?

Manufacturers claim that lower profits will mean less research. But why should that be? This claim uncannily resembles that made by local officials demanding tax increases as the only way to avert layoffs of police officers and firefighters. Why is it that other public workers are less often targeted publicly for budget-balancing layoffs?

Americans may not agree with the drug companies' priorities. Lower drug prices and profits in the U.S. do not have to translate into less money to invest in needed research. Other drug company responses are possible:

- As is discussed elsewhere, when governments in the United States begin to protect citizens
 by negotiating lower drug prices, the drug makers can and should be expected to ask other
 wealthy nations to begin paying their fair shares of research and profit costs.
- Lower U.S. prices will result in higher private prescription drug use in the United States.
 Lower prices will allow more patients to buy more drugs with their own money. This reasonable response, which economists call price-elasticity of demand, will be discussed later in this report.
- Further, companies could adapt to lower U.S. prices by cutting some of their overhead and other costs. For example, in 1997, drug industry total direct compensation to CEOs averaged 39 percent higher than would be expected in light of—controlling for—company size and company financial performance.⁶⁷ And it appears that the total compensation of the ten best-paid drug company CEOs amounted to \$229 million in 1997,⁶⁸ or nearly one-fifth of the manufacturers' total incremental cost—their real cost—for the \$18.5 billion drug donation program discussed later in this report.
- Lower overall profits might inspire *more* research as a means of raising profits, if developing new breakthrough drugs were properly rewarded.

The high level of drug industry profits every year, and especially since 1986, raises the question: where is the risk? Risk implies uncertainty. While some uncertainty may surface among individual firms, it is certainly not apparent across the industry. Therefore, the extraordinary rate of return does not seem to be justified by the risks run.

The drug companies say they need high profits to compensate them for the great risks they take in developing many medications, only a fraction of which become substantial money-makers. But drug companies are no more likely to face bankruptcy than other U.S. businesses, and financial analysts have tended to rate drug company stocks as less risky investments than other stocks. The U.S. Office of Technology Assessment found that average returns of U.S.-based, research-intensive pharmaceutical firms exceeded returns of other types of firms *even after adjusting for differences in risk*, over twelve years. In the 1980s, the drug manufacturers garnered profits that "more than offset" the costs and risks of research and development. Noting that OTA's data suggested that pharmaceutical returns averaged 15 to 30 percent above levels needed to attract sufficient investment capital, *Consumer Reports* concluded that "prices could come down without damaging the industry." And it is useful to appreciate that the OTA analysis could not include the 1990s, years of very high profits.

The drug companies understandably exaggerate the risks they face. They do so in at least three ways.

• Anxious to justify their disproportionately high profits, the drug manufacturers exaggerate the returns they require to attract capital to bear the risks they face. The development of an individual drug may well be risky. But since industry profits have been very high, year after year, in good times and bad, as just noted,⁷² how great are their real risks, when averaged across all their drugs under development? The companies spread risks by developing many possible products. Viewed in this way, the risk level does not appear very great. Imagine that the average gambler returned from the casinos with a substantial profit each year. Would that be a risky business for the gamblers?

Therefore, the drug makers' real needs for profits should be gauged mainly by one measure: What profit level do they need to attract and retain capital sufficient to operate successfully in the public interest by developing and producing innovative, effective, safe, and affordable medications? That is an empirical question—one that the manufacturers should be asked to answer whenever they argue that their high profits are vital to all Americans.

- They lay off risk by relying on the federal government or on separate and smaller companies to finance much of the riskier early-stage research on possible drugs. In the United States, public investment in bio-medical research, much of it supporting the development of new prescription drugs, appears to be much greater than elsewhere, whether measured by dollars per capita or by share of health spending. The differences are dramatic. For example, U.S. NIH spending in FY 1999 was \$15.600 billion, Canadian government research biomedical spending in FY 1999 was \$0.690 billion, and U.K. National Health Service and Medical Research Council research spending in FY 1998 was \$1.230 billion.⁷³
- The drug companies actually devote surprisingly small shares of their outlays to what is
 risky—scientific research—as opposed to marketing research, actual marketing, and profits.
 Public Citizen reported recently that all of the ten largest U.S. pharmaceutical makers
 retained more money as profit (net income) than they used for research and development.
 Among those firms, half had profits at least 1.5 times as high as their R&D spending.⁷⁴

And on the role of marketing and administrative costs, consider Exhibit 11, which displays how Merck and Pfizer—the first- and fourth-largest drug makers in the U.S., with combined revenues of over \$40 billion⁷⁵—allocated their revenue in 1997.

Merck and Pfizer devoted an average of only 11.2 percent of revenue to research and development, while marketing and administration consumed 28.9 percent. Profit (net income), at 18.6 percent of revenue, was also far above R&D spending.⁷⁶ And marketing costs can be expected to rise further in the future, with the explosive growth of direct-to-patient advertising and the renewed use of detailing sales staff to approach physicians.

Schondelmeyer has stated that the drug makers' revenue dollar typically breaks out in this way:⁷⁷

research and development	20 %
marketing and advertising	20-30 %
profit	15 %
general administration	10 %
manufacturing (average cost)	5 – 25 %
tax	8 %

But research and development is a very broad category. The U.S. Senate Committee on Aging concluded that "many of the dollars that drug manufacturers claim are spent on research of new pharmaceutical products are actually spent on marketing research"; this involves gathering data for "design [of] their lavish marketing and promotional campaigns," rather than for "development and discovery of new drugs." Through this deception, manufacturers gain not only the public relations value of appearing devoted to research, but – far more valuable – by expanding the tax credits that they can claim, they also reduce their tax bills.⁷⁸

The pharmaceutical industry itself acknowledged that drug companies in 1991 expected to spend more on marketing and advertising (an estimated \$10 billion) than on research and development (\$9 billion).⁷⁹

Among 15 of the largest international drug makers, all had marketing, selling, and administrative expenses in 1993 that were at least 78 percent above their own claimed expenditures on research and development, and fully half acknowledged spending three or more times as much on these non-production, non-research activities as on research and development. (The average reported by these 15 firms was \$3 billion for marketing, selling, and administration, as compared with \$925 million for research and development -- and the R&D figures are, as just noted, often inflated by counting market research costs as research.)⁸⁰

d. Lack of competition. Another reason why prescription drug prices are high is lack of competition. Patent laws appropriately grant government-authorized monopolies to drug makers for new products, in hopes of encouraging innovation. But that gives those drug makers substantial power to control the prices they charge. In other nations, governments have recognized that this monopolistic or oligopolistic pricing power must be offset by government action to keep drugs affordable and to approximate price levels that would be produced by a genuinely free market. That has not happened yet in the United States. Further, market

observers have suggested that a large number of therapeutic clusters of medications are either monopolized or dominated by a small number of manufacturers.⁸²

Brand name drug manufacturers make concerted efforts to reduce competition. For example, some manufacturers are seeking to convince legislators to prohibit substitutions of certain generic drugs for brand name drugs, over-riding Food and Drug Administration decisions that they are equivalent. They also seek patent extensions (sometimes through political action in Congress rather than on any technical merits) and use lawsuits and other means to delay entry of multiple generic competitors into the market. A proposal now before Congress to delay the patent expiration on seven drugs is likely to cost American patients and other payors between \$2.2 billion and \$4.5 billion over three years, one analysis found. 83

Another study concluded that the refusal of Congress to eliminate an originally unintentional windfall to drug makers—two-year patent extensions for many drugs that resulted from provisions of the 1994 General Agreement on Tariffs and Trade (GATT)— would cost U.S. patients and payors about \$550 million in 1997 alone. The estimated cost of delaying the market entry of lower-cost generic competitors over 17 years is \$6.2 billion.⁸⁴

Finally, there is an important barrier to international trade and free competition for prescription drugs—another clear departure from a free market. The U.S. prohibits pharmacies (and everyone else except drug makers) from importing drugs that are sold at lower prices in other countries. If permitted, offering such imports for sale here could allow Americans to benefit from the lower prices that other countries negotiate; the prohibition is another clear departure from a free international market for prescription drugs.

<u>e. Manufacturers' pricing strategies</u>. Because drug prices are not set in direct relation to research and development costs, it is not appropriate for the manufacturers to claim that high prices are necessary to finance their research. The "pricing strategies" that drug companies use may have "little relation to the development costs," especially for newer drugs, noted the pharmacy director of Arizona University Medical Center. "Newer agents are being priced to compete with alternative treatments such as surgery, hospitalization, increased ICU days, lost productive time from work, and market factors." ⁸⁵

Supporters of that strategy assert that a new drug with "potential to prevent a hospitalization . . . has every right to be priced for value, not cost," and that such pricing is essential to stimulate investment in drug research. But that view ignores the people who could not afford to use the new drugs, if priced high, and ignores evidence that rewards for pharmaceutical investors are already ample.

A Mayo Clinic physician exposed a striking case of charging what the market will bear. He reported that levamisole, a drug developed by Johnson & Johnson to treat sheep for worms, was the only drug known to be effective in humans in preventing recurrence of colon cancer after surgery. Patients need to take levamisole for a year, and for a year's supply, Johnson & Johnson was charging nearly \$1500. But if the same amount of the same drug were purchased from a competitor for treating sheep, the Mayo physician noted, the price would be just \$14 and change— so people were being charged 100 times the price of the identical drug for animal use. If the roughly 20,000 good candidates for this colon cancer treatment every year received it, he estimated, 7,000 deaths could be prevented.⁸⁷ The AAMP calculates that Johnson and Johnson would reap \$30 million annually for 20,000 patients—instead of the \$300,000 charged if the patients were sheep. But it is likely that some Americans have been

dying because they have been unable to afford that inflated price.

Another indication that drug prices are not fundamentally research-linked: price increases for older medications were responsible for half the industry's revenue growth in the 1980s. A U.S. Senate analysis found that drug manufacturers were imposing large price increases – possibly even the highest increases – on "drugs that have been on the market for many years, for which research and development costs have long since been recovered." For example:

two of the biggest-selling drugs, "Premarin (an estrogen replacement therapy) and Inderal (a heart medication), both manufactured by Wyeth-Ayerst, have been on the market since 1956 and 1967, respectively. [From 1985 to 1990,] Premarin went up in price...an average of 21.5 percent each year, and Inderal...an average of 17.1 percent...." Wyeth and Ayerst, and their merged successor, brought only one new molecular entity to market in those five years. ⁸⁹

On a related point, note that manufacturers' prices for drugs are not closely linked to the cost of production, either. A striking illustration is the anti-cancer drug, Taxol, developed through federally-funded research and licensed to Bristol-Myers Squibb (BMS) to market. A full course of treatment with Taxol could cost \$9,000 at the BMS wholesale price. Under contract with BMS, however, another company was actually producing the Taxol for one-twentieth that wholesale price. ⁹⁰

Some observers conclude that even generic drugs commonly are priced well above the cost of production. This has been in part because the companies making brand-name drugs often produce generic versions as well, or they buy or control the generic makers through stock ownership. A 1993 report indicated that brand-name companies owned about 70 percent of the generic drug industry, and that share was growing.⁹¹

The price of Taxol (and the high prices charged by Burroughs-Wellcome for the anti-AIDS drug AZT) highlighted concerns about another issue: the pricing and royalties for commercially-licensed drugs arising from federally-funded research. The Office of Technology Assessment concluded in 1993 that federal policies were inadequate to protect the public's interest in affordable drug prices and reasonable compensation for federal investments in research. Flying in the face of this conclusion, however, the National Institutes of Health abandoned the little leverage that the government had over prices for such drugs. In April 1995, NIH gave up its right to require "reasonable pricing" by drug companies for medicines developed through either government research or industry- government collaborations.

2. Why are Many People Unable to Afford Medications at Current Prices?

Many people cannot afford medications because U.S. prices are so high. And Americans who lack insurance for prescription drugs pay prices substantially greater than the U.S. average price. That is because manufacturers and retailers are often forced to grant discounts to advantaged payors. The Veterans Administration, Ryan White Program, other federal programs, and the federal – state Medicaid programs obtain lower prices through federal legislation. Hospitals and HMOs and pharmacy benefit management companies (PBMs) have often been able to negotiate discounts or rebates that lower somewhat the effective prices they pay. In the face of these discounts, manufacturers and retailers extract higher prices from all those Americans who buy their drugs out-of-pocket. As these Americans often suffer low

incomes, they are disproportionately likely to lack the money to pay these higher prices. It is hard to imagine a less just arrangement—especially considering that U.S. drug prices are the world's highest overall.

This problem is magnified by the surprisingly unequal distribution of income in the U.S.

- Our incomes are the most unequal in the industrial world. The main measure of income equality is the Gini index (or Gini coefficient). When incomes are entirely unequal, the Gini index is 100.0. When incomes are entirely equal, the Gini index is 0.0. So the higher the Gini index, the worse a nation's income inequality. Among the 17 wealthy nations in the Organization for Economic Cooperation and Development for which data were available, the United States suffered the highest Gini index. The U.S. index in 1994 was 40.1, one-third greater (less equal) than the average of 29.7 prevailing in the remaining 16 nations.⁹⁴ The Gini indices for OECD nations are shown in Exhibit 12, "Income Inequality, OECD Nations Whose per Capita GDP Exceeded \$15,000, 1982 1994."
- Within the United States, Gini indices have risen over time. For families, they have gone up from 36.1 in 1969 to 41.4 in 1989. For households, they have gone up from 41.5 in 1979 to 44.5 in 1989. §5
- Among these United States, it is also worth noting that Gini indices vary very substantially from state to state.⁹⁶ In 1989, for example, Gini indices for household income ranged from 38.5 in New Hampshire to 47.6 in Louisiana. They are generally lower in New England, the plains states, and the midwest, and higher in the south and southwest. (Eight of the ten states with the least equal family incomes in 1989, for example, were in the south.) Efforts to assure financial access to prescription drugs would probably be particularly helpful to the residents of those states with less equal income distributions, and in the states with lower real incomes, adjusted for both overall costs of living and cost of prescription drugs.

Outside the United States, wealthy nations provide financial protection against the cost of prescription drugs for virtually all residents. But in the United States, the inequality of income with which to buy prescription drugs is magnified by the widespread lack of coverage for prescription drugs.

Over one-quarter of all Americans lack insurance coverage for prescription drugs, as noted in the preceding section. Our nation is unusual in its lack of universal financial protection against health costs. And this is especially remarkable since our overall health spending per person is more than double the average of the world's other wealthy nations.⁹⁷

3. Underlying Reasons for the Failure to Make Needed Prescription Drugs Affordable

For many reasons, Americans have been unable or unwilling to make prescription drugs more equally affordable by securing lower prices or by ensuring that purchasing power be more equitably distributed. The underlying causes of this failure include:

Governments' relatively small responsibility for paying for medicine for people. This has
meant that government has not felt much direct pressure to intervene to win lower prices
from the drug companies. Most important, the federal Medicare program, whose enrollees
often need a great deal of medications, has only covered outpatient prescription drugs under

very limited circumstances (anti-rejection drugs for transplant patients, for example ⁹⁸). The federal government has secured lower prices for itself when it does pay for drugs— especially for the Veterans Administration and somewhat smaller reductions for Medicaid. Some state governments that finance small pharmacy programs to buy drugs for seniors have won Medicaid prices for these drug purchases. Otherwise, governments have been largely indifferent until recently.

- Failure to take responsibility for cost control. The just-described insularity dramatically manifests the traditional posture of American payors for health care—one of competing to avoid costs and to shift them onto other payors, rather than one of inter-payor solidarity in bargaining with caregivers.
- The political power and campaign contributions of the drug manufacturers. Manufacturers fight public efforts to win lower prices. They even oppose public programs that would finance the purchase of medications if they fear that establishing those programs might subsequently motivate government to work for lower prices (to make those programs more affordable to government). In this spirit, for example, the manufacturers have opposed the 1999 Kennedy Stark proposal for a new prescription drug benefit under Medicare. 100
- PhRMA's fog of fear: The smokescreens and scare tactics of manufacturers. The drug manufacturers have suggested that if Americans did not pay the high prices that "bear the world's research burden," many effective new medications would not be developed. Alan F. Holmer, PhRMA's president, has written that reducing U.S. drug prices would mean that Americans "will see more illness and higher overall spending on health care." He has said that price controls will block the development of "new, innovative medicines." The president of the Biotechnology Industry Organization claims that "Price controls [under Medicare] limit profits. If profits are not possible, investors stay away. If there is no money for research, new treatments are not developed. The elderly—the people Medicare was designed to protect—suffer."

International fairness. Yet lower U.S. prices would not automatically reduce total revenue and profits for drug manufacturers. They could respond to a drop from today's high U.S. prices in several ways intended to maintain revenues, or at least maintain profits, including options discussed later such as raising sales volume or cutting costs. Drug companies may also recognize that there is no reason why Americans should disproportionately finance the companies' profits—or research. So one important way the drug makers could maintain revenues and profits is by seeking to raise prices in other wealthy nations. The result would be price equality in rich countries. (Raising prices on poor countries would gain the companies little or nothing, of course, since poor countries generally cannot pay any more.)

High U.S. prices cannot explain allegations of higher innovation in the U.S. Holmer's assertion that other wealthy nations' "public utility" controls on drug prices dampen research¹⁰⁵ flies in the face of the face of the realities of the international drug market. Manufacturers in all wealthy nations earn a disproportionate share of their profits in the United States. All manufacturers respond to the same set of pricing policies worldwide. One very different force stands out as a more plausible candidate for the engine of U.S. drug innovation—the extraordinarily high level of public financing for biomedical research in the United States from the National Institutes of Health.

Further, the choice is not between today's extraordinarily high profits and no profits. Nor is the choice between today's high profits and no research. *There are middle grounds*,

reasonable middle grounds. PhRMA's failure to mention these is not surprising, since PhRMA's first duty is to its member companies. And their own first duties are to their stockholders.

Affordable innovation. PhRMA cites with approval Danzon's claim that price controls stifle innovation. Yet this claim does not make sense. For example, if—as is true in many nations today—prices remained high on genuine breakthrough drugs, but were lowered for copy-cat drugs, more money would be channeled into productive research. If prices fell in the U.S. but rose in other wealthy nations, drug company revenues and profits could remain steady at today's very generous levels. And having price controls in some nations does not stifle innovation because all manufacturers compete in a global market. All the industrial world's manufacturers have access to the U.S. market's high prices. All the industrial world's drug manufacturers therefore earn a markedly disproportionate share of their profits from American patients and American payors. Why, then, should only some be spurred to innovate? (The U.K.'s drug industry, for example, has been highly innovative even though its domestic profits are regulated.) If indeed there is an international variation in the level of innovation, the explanation cannot lie in higher U.S. prices; it must be sought elsewhere.

The drug manufacturers claim that their extraordinarily high profits are necessary to finance innovation to develop promised breakthrough drugs. That does not appear to be true, given the low share of the revenue dollar that drug makers actually devote to research. But high U.S. prices are a principal foundation of those high profit levels. One consequence of high U.S. prices is that today's American patients are being denied affordable drugs. Will they be any more likely to be able to afford tomorrow's drugs?

Reality, not rhetoric. The drug manufacturers also claim that any public program to make medications affordable would be bureaucratic, wasteful, inefficient, and expensive. Apparently anxious to capitalize on anti-government emotions, PhRMA claims that proposed Massachusetts legislation to win price discounts and rebates would "bring the inefficiencies of a large-scale government-run program to all Massachusetts residents seeking drugs. The Massachusetts program means "big government" bureaucracy for all Massachusetts residents, even those privately insured." Yet the Australian government needs only six people to staff its price negotiation systems. In Massachusetts, the commissioner of the state Medicaid program said that he could piggy-back the administration of the proposed price discount and rebate legislation on top of existing Medicaid mechanisms at very low administrative cost. 109

- Frittering away energy and resources on attempted solutions that may be helpful in some respects but that are not adequate to make prescription drugs affordable. For example, many of the efforts to contain costs of prescription drugs in the U.S. have focused on the retail level. Generic substitutions have been mandated. Retailers' profit margins have been squeezed even though U.S. retailers are generally considered among the most efficient in the world. Further, only about one-quarter of the total retail dollar remains at the retail level. The manufacturers garner about three-quarters of every retail dollar. Strategies to contain prices need to address the source of high prices—the manufacturers themselves.
- The myth of a free market for prescription drugs (despite the manufacturers' patent monopolies and oligopolies¹¹¹, as discussed earlier) reinforces the usual American preference for market and dislike of government.¹¹² If we enjoyed a functioning free market, this preference would make sense. As a free market is lacking, market rhetoric becomes a

smokescreen behind which the world's drug manufacturers harvest extraordinary profits from American patients. Claiming that a free market functions, the manufacturers claim that high profits are required by the high level of risk that they assume. But without either a functioning free market or effective government intervention, anarchy ensues. Anarchy allows those with power—drug makers with monopoly or oligopoly power—to raise prices and profits above free market levels. This probably does much more to explain the drug industry's high profits than do claims of risky investments or innovative research.

D. WHAT PRIVATE, FEDERAL, AND STATE SOLUTIONS ARE POSSIBLE?

High drug prices and lack of insurance coverage or of private resources leave many Americans unable to afford needed prescription drugs. This problem will probably worsen in the years ahead because prices will continue to rise as high-priced new medications are marketed, and insurance coverage is likely to fall, partly in response to high prices.

As noted near the beginning of this report, three types of responses to the problem are possible: suffering, more money for manufacturers, and more affordable medications. The first is not acceptable. The second solution is not affordable and is not necessary. That leaves the third.

Since present U.S. spending on prescription drugs is (in our judgment) sufficient to pay for the types and amounts of medications that Americans need, then the challenge is to devise methods of obtaining those drugs from manufacturers without spending more money and without reducing manufacturers' profit margins so much as to endanger the flow of capital adequate to finance needed research. Some proposals would lower prices for various groups of patients. Others would secure greater volumes of medications.

1. Recommended Solutions

<u>Discounts.</u> Generally, proposals to lower prices for various groups of patients would make medications more affordable. They would provide the most help to people on the edge, those who are struggling to pay for needed medications. But even the largest contemplated price cuts—of 40 percent or so—would provide less effective help to people who can't come close to financing their annual prescription drug bills—those who require very costly medications for the long term and could not afford even prices discounted so deeply as 40 percent. These proposals would also lower manufacturers' revenues, although such reductions would be partly, or possibly entirely, offset by the higher sales volumes engendered by lower prices. Indeed, lower prices would increase drug sales substantially—perhaps by amounts more than sufficient to offset completely the revenue losses caused by the discounts.¹¹³

Rebates. Proposals to secure greater volumes of medications without spending more money are targeted at people who would not be helped sufficiently by lower prices alone. So far, these proposals are generally less well-developed than those to lower prices. Some, as in Massachusetts and Vermont, would extract rebates from manufacturers and recycle the money to buy more drugs from the same manufacturers. These plans recognize both the very low marginal cost of manufacturing additional pills and the already very ample revenues of the drug makers.

Rebates could be in cash or in kind. That is, manufacturers could be asked to pay a cash rebate to a trust fund, which would then be used to buy medications and pay dispensing fees to pharmacies. Alternatively, manufacturers could be asked to post letters of credit, equal to perhaps 25 percent of the average wholesale price of their retail sales in a given jurisdiction. Physicians would prescribe needed medications to patients who could not afford them, and the cost of these medications would be debited against the manufacturers' letters of credit. Manufacturers would have to make more medications, but this would be a small burden because (as discussed in a later note) the marginal cost of almost all drugs is very low. The AAMP estimates it at five percent of average retail price.

As shown shortly, providing 25 percent more medications in the United States would cost the world's drug manufacturers only about \$1.25 billion. If the twelve largest U.S. manufacturers alone had borne this entire burden in 1998, their combined profits would have fallen by \$1.25 billion—the cost of manufacturing the additional medications. This would have dropped their overall profits from 17.6 to 16.8 percent of total revenue, leaving their profits securely in first place among U.S. industries. Americans would have gained \$25 billion in new prescription drugs, measured at retail prices—without increased taxes, premiums, or out-of-pocket payments. Additional costs for retail dispensing would have to be financed.

Who would pay dispensing costs? The three main options are to take the needed money from the cash or credited rebates, ask patients to pay, or use existing or new public funds to pay pharmacists' legitimate dispensing costs. If discounts markedly reduce manufacturers' revenues, it would be less fair to ask them to shoulder this additional burden. Even paying for dispensing at a rough marginal cost estimate of \$5 per prescription filled, 114 dispensing costs could total perhaps \$3.125 billion. This assumes the \$25 billion in new prescriptions retail at an average of \$40 each, and thus represent about 625 million additional prescriptions filled. (Despite many closings in recent years, pharmacies are in place already in many communities 115 to fill this anticipated 625 million prescriptions, but large numbers of additional pharmacists may be needed.)

Similarly, if discounts were substantial but price elasticity of demand proved insubstantial, manufacturers' revenues and profits would suffer considerably. It might then be more appropriate to complement the discounts and rebates with increased public payments to buy medications for people who cannot now afford them. But the underlying principle should be that manufacturers' total revenues should not rise after all discounts and rebates are considered.

To summarize: The AAMP suggests these aims for and constraints on policies to reform prescription drug financing in the United States:

- 1. Assure that all Americans are able to afford needed prescription drugs.
- 2. Do so without increasing manufacturers' total revenues from public and private sources together.
- 3. Manufacturers' profits should remain adequate to attract capital required to finance all needed research.

The challenge, therefore, is to blend the two approaches—discounts and rebates—to secure needed drugs without spending money unnecessarily—and without disrupting the flows of revenues or profits that manufacturers need to finance needed research. For example, the greater the price discount, the less money manufacturers can afford to rebate to finance greater volumes of drugs, other things equal. But other things need not be equal. For example, federal or state governments might regulate or negotiate discounts to lower drug prices. They might also appropriate more public money to buy drugs for people who cannot now afford them. Or they might finance publicly the costs of dispensing the additional volume of needed medications. The result might be that manufacturers' total revenues would remain the same as they are today.

The next section of this report describes and briefly analyzes nineteen different public and private methods of winning lower drug prices and seven ways of winning improved drug

coverage. The analysis here gives greatest attention to reforms that will not increase spending and that preserve manufacturer profit margins adequate to finance all needed research.

2. Comprehensive Inventory and Assessment of Possible Solutions

Today, many Americans cannot afford the prescription drugs they need. This is owing to a combination of high prices and lack of insurance coverage or private resources. Many private and public efforts have been launched or proposed to ameliorate these problems. The following four-part table simply classifies current or future ways to a) win lower prices and b) cover more people. The table identifies which interventions would be public and which would be private.

CLASSIFICATION OF POSSIBLE SOLUTIONS

	a. PRIVATE	b. PUBLIC (F = federal; S = state)
1. WIN LOWER PRICES	 Patients ask physicians for cheaper medications physicians prescribe greater quantities, dosages patients shop pharmacies by price for different drugs capitate physicians for drugs use more generics payors seek better deals for themselves, partly by setting restrictive formularies voluntary buying cooperative higher co-pays, add 3rd tier lower ceilings on covered drug costs squeeze retailers; cut prices 	 allow patients access to Federal Supply Schedule (FSS) prices F S buy from native Americans at FFS S allow access to Medicaid prices F S allow access to prices negotiated for public employees F S pool all buying power to negotiate prices with manufacturers F S join in purchasing compacts with other states or with Canadian provinces S regulate drug prices F S buy drugs for all patients S import or re-import FDA-approved drugs via Canada or Mexico S
2.COVER MORE PEOPLE	 buy health insurance that covers drugs use drug manufacturers' charity distributions through physicians 	 subsidize drug purchase with general revenues, tobacco settlement, or similar new funds S new Medicare drug benefit F voluntary or mandated insurance F S negotiate rebate from manufacturers; recycle to buy drugs for people who can't afford needed drugs F S negotiate with manufacturers for more drugs for same dollars F S

A few notes on the classification of possible solutions:

- Some of the interventions are included even though they do not neatly fit this simple four-part classification. For example, at least two of the private techniques to lower prices are really designed to shift physician prescribing patterns or patient requests toward medications with lower prices. HMOs are raising co-payments on many medications and adding a higher third level of co-payments of perhaps \$25, \$30, or even \$50 per prescription. (These may prompt patients to second-guess their doctors by failing to fill their prescriptions.) And some HMOs plan to build the cost of prescription drugs into their capitated payments to physicians. By placing physicians at risk, it is hoped that they would select less costly medications.
- Most of the interventions included in the four-part classification are designed to win short-term relief by addressing the immediate problems of high prices and patients' inability to afford needed drugs. The interventions designed to win long-term reforms—such as negotiating an international prescription drug price treaty, designing research priorities with patient need and affordability in mind, ascertaining fair rates of return to manufacturers (commensurate with real risk), improving physician prescribing by securing better evidence on benefits and costs of medications, outlawing direct-to-patient advertising, and improving patient use of drugs—are discussed separately at the end of this section.

a. To Win Lower Prices

a. (1) Private techniques to win lower prices

The U.S. drug industry urges that patients take three steps to save money on prescription drugs. 116

- "Be frank with your doctor about your financial status. Tell the physician that though you want the most cost-effective therapy, you are also concerned about your budget.
- "If you have a chronic illness that requires taking medicines over a long period, ask your doctor to prescribe a large quantity to cut costs.
- "Shop around. In a February 1996 survey, New York City's Commissioner of Consumer Affairs found that the price of a sampling of 20 prescription drugs varied as much as 300 percent in different drugstores in the same city."

While each of these techniques has some value, each is seriously flawed. It is easy to preach frank conversations, but many patients will be reluctant to launch them and many physicians are not comfortable in participating. And *do the manufacturers really want to preach second-class therapies to patients with second-class financial status?* What would be the point of undertaking all that vital research, especially the share supported with National Institutes of Health financing, if some patients can't afford the resulting medications? Further, shouldn't all patients want the most cost-effective therapies?

Finally, this PhRMA exhortation assumes that physicians have the information—or the time to obtain it—needed to identify the most cost-effective therapy. Yet that information is very often lacking today.

It is hard to object to PhRMA's second recommendation. But it faces practical implementation difficulties. Many insurors or HMOs limit patients to a 30-day supply of a medication (perhaps because they want to increase patient co-payments' share of total drug costs). In a variation on this approach, two Nevada HMOs recently advised their physicians to prescribe higher-dose tablets of certain medications. Patients were mailed simple tablet-splitting devices. Some physicians objected to this procedure on grounds of patient safety. It remains to be seen whether this approach saves money in the short run or is safe. In the long run, though, if patients or HMOs do save money, manufacturers can be expected to raise prices on the higher-dose tablets to make up for lost income.

PhRMA wants patients to price shop for drugs at retail. If they can find drug stores with good service and consistently low prices, PhRMA's advice would be sound. But in practice, it may well be that some drug stores offer lower prices on certain medications while other drug stores offer lower prices on other medications. To save money, patients would have to disperse their purchases. This would tend to fragment important information about possible drug interactions among several pharmacists, and also undermine patient-pharmacists relationships. That might be dangerous to patients.

<u>Capitate physicians for drugs</u>. When HMOs negotiate capitation arrangements with physicians, they agree to pay each physician a certain amount per patient per month, regardless of services used. Sometimes, primary care physicians are capitated for their own services and are also at risk for a share of the costs of specialists' services, tests, or hospital care. Primary care physicians—and even some specialists—could be put at risk for the cost of prescription drugs as well.

This would tend to induce physicians to prescribe less costly drugs, unless they feared that doing so would cause the patient to need physician, hospital, or other care that would, on average, cost more money than the amount saved on drugs. But lack of evidence on costs and efficacy of different drugs—and other treatment patterns—would make it hard for doctors to make rational calculations about which drugs were most cost-effective on balance. As a result, many physicians might tend to make their judgments on stark financial grounds: which drug will leave more money in my pocket. But other physicians might be risk-averse and prescribe what they believe to be the most efficacious drug regardless of cost (or perhaps because it cost more) to forestall possible malpractice litigation down the road.

<u>Use more generics.</u> This is a helpful strategy, one advocated for at least a third of a century. ¹¹⁸ But because it has already been widely implemented, it will probably be hard to employ it to win substantial additional savings. According to PhRMA, generics grew from 18.6 percent of all prescription units ¹¹⁹ in 1984 to 46.5 percent in 1998. ¹²⁰

Moreover, the manufacturers have taken a number of steps to slow generic substitution. They advertise and market and lobby to promote their brand names over generics. They patent minor variants on drugs whose patents are expiring and then market those newly patented drugs heavily. They raise questions about the efficacy of some generics. They have won new laws in some states that prohibit pharmacists from filling prescriptions with generic equivalents without calling physicians first. They also win Congressional extensions of patent protections, delaying the introductions of generic substitutes. In some cases (particularly during litigation), they even pay generic manufacturers to keep their low-cost competitor drugs off the market.

<u>Payors seek better deals for themselves.</u> Several tactics can be used here. Since HMOs and insurors must compete for patients by price, they are anxious to hold down their costs. Since prescription drugs are becoming a steadily larger share of their costs, HMOs and insurors are working harder to hold down spending on medications.

One technique they use is to negotiate a rebate from manufacturers in exchange for taking steps to increase use of that manufacturer's products. This can include the establishment of formularies that exclude certain products or make them more difficult to use. Periodic changes in formularies (as deals are re-negotiated) may require patients to change medications, causing health problems for some, and even necessitating costly physician or hospital care.

Some physicians resent formularies when they interfere with preferred prescribing patterns. But unless physicians are salaried or capitated by the HMO, it can be difficult to change their prescribing habits. Managed care organizations are likely to find it harder to channel patients to certain drugs over time, as their relations with physicians are likely to become looser, not tighter, with the growth of the less restrictive preferred provider organization and point of service options.

Some argue that HMOs and other payors should be able to marshal their purchasing power through pharmaceutical benefit management companies (PBMs), and thereby secure lower prices. While this theory is attractive, the practice seems less so, for two reasons. First, PBMs will naturally try to retain for themselves a share of any discounts or rebates they obtain. And second, manufacturers have bought several of the large PBMs, making it less clear who those PBMs are working for.

As individual payors seek better deals for themselves, manufacturers and retailers respond by raising prices (shifting costs) to payors and individuals with less bargaining power in the marketplace. If PBMs or individual payors—such as the federal government through its Federal Supply Schedule negotiations, the federal-state Medicaid programs, or individual HMOs—win discounts from manufacturers, manufacturers can be expected to try to raise prices on other payors.

And if some payors or PBMs win lower prices from retailers, the retailers are likely to respond by raising posted charges for people who lack a powerful payor to bargain on their behalf. Most prominent among these people are the 70 million Americans without insurance for prescription drugs. Thus, lower retail prices for some patients mean higher prices for other patients.

The domestic cost shift by manufacturers and retailers within the United States closely parallels in its causes and its mechanics the international cost shift that has produced the world's highest prices in the United States.

<u>Voluntary buying cooperative.</u> Payors would gain market power if they were to join together when they bargain with manufacturers or retailers. Were this legal—were it not deemed a conspiracy in restraint of trade—it would lower drug prices for members of the cooperative. Courts worried about high drug prices might find these arrangements to be legal. (In a sense, PBMs are designed to win some of this advantage legally, but savings could be compromised for the reasons just described.) The better the deal won by the cooperative, the more members it would attract. This would increase its market power and win still better deals. Drug makers

might refuse to bargain with buying cooperatives, but they would probably violate anti-trust laws if they joined together to refuse.

Charging patients higher co-payments overall, and making special charges for more costly drugs. Some HMOs and insurors are raising their co-pays. This is a regressive tax on people who become sick and need medications. Patients seldom choose their medicines; physicians overwhelmingly do. There is little practical justification even for maintaining a higher co-payment for non-generic brand name drugs. All of this supposes that patients can be turned into battering rams to help capture the fortress of high costs. And it supposes that physicians will know enough about patients' insurance coverage and personal finances—and about medications' comparative cost-effectiveness—to respond to high co-payment schedules by prescribing more rationally.

Patient cost-sharing requirements, the evidence indicates, deter necessary as well as unnecessary care— so the U.S. OTA called them a "crude instrument," attacking health care utilization indiscriminately. For example,

- The Rand Health Insurance Experiment, the unique randomized trial of the effects of different types of health coverage, found that cost sharing 125 had "equivalent effects in curtailing use of highly effective and only rarely effective medical care...." The experiment yielded "no evidence that the imposition of cost-sharing led individuals to make appropriately selective decisions...." 126
- In quasi-experiments, introducing prescription drug co-payments has significantly cut use of cardiovascular and other vital drugs, sometimes more than the reductions in prescriptions for symptomatic relief.¹²⁷
- Cost sharing is especially likely to reduce low-income patients' use of care. But even non-poor adults in cost-sharing plans in the Rand Health Insurance Experiment had significantly lower use of highly effective acute care than did those in free care plans.¹²⁸

Care and medications used for preventive purposes may be especially vulnerable to the deterrent effects of patient cost-sharing requirements. 129

Squeeze retailers through selective contracting, laying off the risk through capitation, mail order, and other techniques. It appears that the retail profit margin on prescription drugs has declined in recent decades. As with generic substitution, it seems to be difficult to win additional savings at the retail level. In a sense, this should not be surprising, since manufacturers take roughly 74 percent of the retail dollar (See Exhibit 13). After paying their costs, the pharmacies' profits are about two percent of the retail dollar. Further, if retailers are squeezed harder still, will pharmacists have the time to counsel patients, check their records for drug interactions, and slow down to avoid errors in prescribing? It seems that the quality of pharmacy services—at least in Massachusetts—has already been threatened by over-reliance on winning price concessions from retailers. Squeezing retailers further unwittingly distracts attention from the main real source of high prescription drug prices: the decisions by the world's drug manufacturers to impose higher prices on American patients.

Squeezing retailers to lower prices is probably one important cause of the decline in the number of pharmacies nationally—especially in the number of independent pharmacies. Nationally, the

number of retail pharmacies per 100,000 Americans has declined by 32.4 percent from 1980 to 1997, from 28.1 to 19.0. This is attributable to the growth of larger chain pharmacies, but also to the gradual cannibalization of smaller family-owned pharmacies.

Ordering medications by phone or on-line and then delivering them by mail seems to reduce prices on those drugs. But this may threaten some pharmacies with closure and both force and allow others to raise their prices. A certain number of pharmacies are needed to:

- provide appropriate access to medications that patients need immediately,
- provide convenient access for frail or ill patients,
- allow pharmacists to counsel patients and check for drug interactions,
- serve patients who cannot use mail order for other reasons (low literacy, limited English, limited vision, cognitive disabilities, and the like), and
- ensure sufficient retail competition by price and quality.

The fixed costs of that number of pharmacies must be covered. To generate the revenue needed to cover those fixed costs, pharmacies will raise prices on that volume of business that remains to them after some medications are bought through the mail. The closing of some competing pharmacies will make it easier for the survivors to raise their prices. If this happens, mail order pharmacy may not save money overall. It may simply redistribute revenue among prescription drug outlets.

At some time, it will be helpful to think through how many pharmacies are needed to assure the delivery of the right medications in a safe and timely manner.

a. (2) Public techniques to win lower prices

Over the past few years, rising spending on prescription drugs has led many people to conclude that private techniques to restrain prices have not been adequate. This has increased interest in identifying, analyzing, and testing a range of public techniques to reduce prices. Some of these are more coordinated and powerful versions of the private techniques. Others are without private parallels. Some are proposed at the federal level, and some in various states. While the mechanics of these bills differ, all would win lower prices. Usually, these would lower revenues to manufacturers, but sometimes pharmacists would be affected.

Access to Federal Supply Schedule (FSS) Prices. On 25 September 1998, Rep. Tom Allen and others introduced the Prescription Drug Fairness for Seniors Act of 1998. This would allow seniors to buy medications at the lowest prices prevailing—the lower of (1) the lowest price paid by any agency or department of the United States or (2) the manufacturer's best price for the drug. In practice, this is likely to be the price paid by the federal procurement system for the Veterans Administration, Ryan White Act programs, and others. (These FSS prices are estimated at less than half of retail, on average. 135)

This approach would respond to the needs of elders plagued by both high use of medications and high charges for individual prescriptions. Because of the domestic cost-shifting described earlier, uninsured Americans, elders prominent among them, pay the world's highest prices for prescription drugs, markedly above the high U.S. average.¹³⁶

The Allen bill has been important in recent months because it has highlighted the problem of prescription drug prices for the public and for Congressional debate. It has brought renewed attention to both the international and the domestic cost-shifts that result from drug manufacturers' pricing policies. And it proposes very substantial discounts for seniors.

In general, price discounts alone would tend to lower the manufacturers' total revenues, other things equal. But other things are not equal. Generally, lower prices of a good or service mean that patients demand higher quantities of that good or service. Economists call this "price elasticity of demand." As noted elsewhere, AAMP estimates of the effects of lower prices on manufacturers' total revenue employ a price elasticity of demand of -0.33. Then, for example, a ten percent drop in price would result in a 3.3 percent rise in demand.

But a recent report from Merrill Lynch has estimated a much greater price elasticity of demand. It is expected, therefore, that if some or all Medicare recipients were to receive a 40 percent discount on manufacturers' prices under the Allen bill or something similar, the manufacturers' total revenue would not be greatly affected. *The change in total revenue would be expected to range between a three percent drop and a slight rise*. These estimates are more optimistic, from the industry's perspective, than our own.

Mechanically, the Allen bill would be simple to administer. The federal government might grant all patients access to the prices that the government negotiates for itself, for Veterans Administration and certain other patients. Politically, it may be difficult. Drug manufacturers are likely to oppose such legislation since they would fear (publicly, privately, or both) that it would seriously constrict their revenue stream. A state variant on this approach would be to seek to negotiate prices with manufacturers that matched those won by the United States. But they would have less bargaining power to do so.

Whether federal or state, this approach secures immediate relief for seniors without raising taxes. Administration is relatively simple, as noted, and it has the additional great advantage of putting the focus on high prices. The disadvantage is that, without further action, it leaves the door open for the drug companies to shift costs from seniors to other Americans. That is, if uninsured seniors—a large share of the market—win lower prices, what is to stop the manufacturers from raising prices substantially on all other people who buy drugs here? The approach to price discounting taken in proposed Massachusetts and Vermont legislation, discussed shortly, would bar such cost-shifting within the state by making the discounts available to all patients, Further, it would prevent manufacturers from raising prices by tying any future increases to the average Consumer Price Index.

<u>Buy from native Americans at the FSS.</u> The Mashantucket Pequot nation is able to buy medications at the FSS for its own members. It is also permitted to resell them to Medicaid patients at FSS prices. The state of Connecticut may become a customer.¹³⁸

Access to Medicaid prices. Medicaid prices for prescription drugs reflect federally-legislated discounts. Federal or state governments might be able to permit all residents—or certain groups of people—to buy medications at these Medicaid prices. This approach closely parallels the preceding; the savings through lower prices would be substantially less. For example, state governments in Massachusetts and elsewhere have won Medicaid prices for drugs bought through existing senior pharmacy programs. More broadly, in June of 1999, the California

Senate voted 29 - 6 to support this approach for elderly or disabled residents. One potential general problem is that if legislative language does not require manufacturers to sell the drugs used by these patients to pharmacies at reduced prices, the pharmacies may suffer financial losses.

Access to prices negotiated for public employees. Some governments negotiate with manufacturers directly or through pharmaceutical benefit managers to win discounts on prescription drugs for public employees. Those governments might allow senior citizens or other individuals to buy medications at these discounted prices. The state house of representatives in Massachusetts recently added a provision to its budget for 2000 that would allow seniors to buy medications at the price negotiated by the state's Group Insurance Commission for state workers and retirees. Increasing the size of the market might enhance its bargaining power, lowering prices further. But the threat of reductions in revenue much more substantial than those associated with discounts to public employees alone might stiffen manufacturers' resistance to offering discounts. As with the solution of providing access to Medicaid prices, a potential problem is that retail pharmacies will suffer financial losses.

<u>Pool all buying power to negotiate prices with manufacturers.</u> Canadian provinces, Australia, and many European nations negotiate or set prices for prescription drugs. Our own federal government, or a state government, could establish itself as the negotiator to bargain with manufacturers over the prices for all people in a jurisdiction.¹⁴¹

Some states and other jurisdictions have begun to do this to buy drugs for patients served by public institutions and programs. In 1985, Minnesota organized a group that has grown into the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP), with 1,900 member jurisdictions in 35 states and an annual sales volume of \$250 million. 142

Massachusetts is considering legislation that would go much further. It would empower state government to use its buying power to negotiate prices for all retail drugs on behalf of all buyers but Medicaid and the federal government. The bill would aim to win discounts of at least 20 percent on drugs under patent and 14 percent on generic medications. To prevent subsequent cost-shifting by manufacturers, a regime of price regulation would be established. Such an approach has been supported by a fairly wide coalition of senior citizens, patient advocates, pharmacists, pharmacies, the nurses association, and others.

Vermont has also held hearings this year on similar legislation. It is said that the drug manufacturers declared their refusal to negotiate with state government were it to pass such legislation. If the manufacturers conspired to do so, that could well constitute an illegal boycott under federal anti-trust legislation, raising the prospect of substantial penalties. Further, it is unpleasant to contemplate the consequences to the manufacturers if patients were to be injured because needed medications were not available owing to a refusal to negotiate. 145

Both the Massachusetts and Vermont bills also include provisions for negotiating rebates from the manufacturers. These would be used to buy medications for people who cannot now afford them. That aspect of the bills is taken up in the next section.

An example. The Massachusetts legislation may serve to illustrate the level of savings that might be won through this approach. The bill in question is H. 2886, An Act to Reduce

Outpatient Prescription Drug Costs and to Expand Coverage; its lead sponsor is Rep. Patricia Jehlen.

This proposal has two parts—to obtain both discounts and rebates from manufacturers for all outpatient prescription drug purchases in Massachusetts. The discounts would mean lower prices for most Massachusetts purchasers. The rebates on all drug purchases would go to a new state trust fund, to finance a proposed new coverage program. The AAMP conservatively estimates that the rebate would raise at least \$300 million to buy medications in 1999. ¹⁴⁶ As a result, other state revenues would not be required, and coverage could be expanded without increasing total spending on prescription drugs. This sum is approximately ten times the current budget of the existing senior pharmacy program for low-income seniors.

The proposal would empower state government to negotiate with manufacturers to obtain discounts of at least 20 percent for sole-source outpatient prescription drugs sold here and at least 14 percent for generic drugs. Manufacturers would also pay a roughly equal sum as a rebate, into a state-managed trust fund. That fund would be used to buy medications for people of all ages who cannot afford them, whether because of low incomes or high prescription expenses. The legislation thus would provide the financing for expanded prescription drug coverage, without requiring either new spending or scarce state revenues. And it would make needed medications more affordable to all.

Because the rebate funds would be used to purchase more prescription drugs, manufacturers would get an estimated 74 percent of the rebate money back, at the cost of producing a few more pills (and their marginal cost is usually extremely low). The volume of prescription drug sales would be boosted not only by the new coverage but also by the reductions in prices. This effect of the price elasticity of demand would increase gross revenues for manufacturers, partly offsetting the effect of the price discount. Thus, the drug manufacturers would lose little.

What would these discounts cost? The AAMP estimates that they would initially reduce manufacturers' revenues by some 18 percent. In 1999, that would be 18 percent of the manufacturers' \$1.85 billion (their estimated 74 percent share of the \$2.5 billion retail drug bill in Massachusetts), or some \$333 million.

But lower prices mean increased sales of drugs. Economists call this a price elasticity of demand. Assuming a -0.33 price elasticity of demand, 147 a 10 percent drop in price would yield a 3.3 percent rise in volume. And an 18 percent drop in price would yield a partially offsetting 5.94 percent rise in volume. This would translate into a \$110 million rise in manufacturers' revenue (5.94 percent of \$1.85 billion). Thus, the net revenue loss to the manufacturers from the discount would drop to an estimated \$223 million.

And patients' benefit would rise even as manufacturers' revenue loss falls. Patients would benefit by the original cut of \$333 million on the original volume of drugs purchased, plus gain the additional benefit of \$24 million owing to lower prices on the new drugs purchased for a total 1999 savings of \$357 million.

Discount Summary

Manufacturers' loss of revenue from discount Manufacturers' revenue gain owing to higher volume \$333 million \$110 million¹⁴⁹

Net loss of revenue to manufacturers

\$223 million

Total savings to patients from lower prices on original \$1.85 billion in drugs from savings on higher volume of drugs

\$333 million \$ 24 million

Gain to patients

\$357 million

The plan also would hold manufacturers' future price increases for existing products to the overall inflation rate. Valuable new drugs could be introduced at appropriate prices.

Learning from the experiences of other nations, such legislation would use the entire state's buying power to balance the drug companies' great selling power, in order to protect Massachusetts patients. The statewide discounts would stop the domestic cost-shifting in drug prices and would start to correct the international cost-shift.

Join in all-patient purchasing compacts with other states or Canadian provinces. Doing so would multiply the purchasing power of the states and, other things equal, would win them greater discounts. The states should therefore consider state-level action. States have surprising purchasing power. As shown in Exhibit 14, California's health spending is greater than France's, New York's is greater than Italy's or the U.K.'s, Texas's is greater than Canada's, and even Massachusetts's is about that of Australia or the Netherlands.

<u>Regulate drug prices.</u> In practice, this may not be very different from the negotiating approach just described. The mechanics would be different, but the aims and political forces arrayed would be fairly similar. States—and the nation as a whole—have the constitutional authority do so, just as states have regulated hospital prices, auto insurance prices, and prices of other essentials.

<u>Buy drugs for all patients.</u> The state of New Hampshire, for example, has established a monopoly on the retail sale of liquor. The state resells liquor at a substantial profit, operating from stores often conveniently located next to major highways. State governments could purchase drugs similarly (but without taking physical possession of the drugs and without disrupting distribution). The states would then resell at no profit, lowering prices substantially. Again, in practice, this may be very similar to the negotiating and regulatory approaches just described.

<u>Import or re-import FDA-approved drugs via other nations.</u> In practice, a great number of medications are sold at retail in Canada, Mexico, and other nations at prices well below those prevailing in the United States.¹⁵¹

Parallel importing is employed throughout the European Economic Community for all goods and services. If one nation is able to win a lower price on any prescription drug, for example, a second nation can import the drug from the first at the lower price. Under a regime of free trade, which seemed to have been won under the North American Free Trade Agreement (NAFTA), it may seem surprising that parallel importing from Canada and Mexico remains impossible. The

U.S. Food, Drug, and Cosmetic Act permits only pharmaceutical companies to import drugs. The putative justification seems to be one of safety. Yet as this restriction applies even to reimportation of medications originally manufactured in the United States, it may have objectives with at best marginal ties to safety.

United States Representatives Marion Berry, Jo Ann Emerson and Bernie Sanders have offered what Rep. Sanders terms "probusiness, free trade" legislation, the "International Prescription Drug Parity Act," to allow U.S. retailers to engage in parallel importing from other nations. The bill would apply only to re-importation of FDA-approved U.S.-made medications that had been sent to foreign distributors. The drug manufacturers worried that the proposal "could lead to the sale of potentially unsafe drugs." Tet the manufacturers had earlier declared their concern that parallel importing would reduce their revenues.

b. To Cover More People

b. (1) Private Techniques to Cover More People

The Pharmaceutical Research and Manufacturers of America urges patients to take two steps:

- "Be aware that health insurance plans vary -- some cover prescription drugs and some do not.
- "If you simply cannot afford your medicine, you may be eligible for one of the many patient assistance programs sponsored by pharmaceutical companies. For a directory of these programs, write to PhRMA, 1100 15th Street, N.W., Washington, D.C. 20005." 155

Buy insurance that covers drugs. This first piece of advice seems somewhat basic. But some Americans who get their health insurance through the job may lose coverage of prescription drugs if their employers find it to be too costly. And seniors most likely to need drug coverage will face rising prices as drug costs climb and as insurors inevitably confront more severe adverse selection—the tendency of people who know they will use costly drugs to buy insurance.

<u>Private charity</u>: the drug manufacturers' drug give-away programs, for some drugs, for some periods, on receipt of a package of letters from your doctor. This certainly benefits some individuals but is not remotely commensurate with the problem. It helps the manufacturers sleep nights, but keeps doctors up doing the necessary paperwork, and keeps patients up worrying whether their petition will be approved, or whether the drug they need will be covered.

If the drug manufacturers desired to offer free medications at volumes commensurate with need, they would cover all medications and simplify program administration. Access advocates have suggested, for example, that the drug companies systematize their efforts and allow a simplified one-stop application process. The manufacturers respond that they had considered doing so, but that their attorneys suggested they would run afoul of federal anti-trust statutes. It is hard to imagine even a star federal prosecutor pursuing such a case on such grounds.

b. (2) Public Techniques to Cover More People

<u>Subsidized drug purchase.</u> A number of states have established tax-financed programs to buy or subsidize prescription drug purchases by lower-income seniors and, in some cases, people with disabilities. Massachusetts is contemplating using part of its tobacco settlement to finance a substantial increase in its program.

<u>Mandatory new Medicare drug benefit.</u> Prescription drug treatments have become increasingly important to older Americans. Sen. Kennedy, Rep. Stark, and others have proposed an important new part of Medicare to help seniors cover their prescription drug costs. This program for all seniors would impose a \$200 deductible each year but then would pay 80 percent of prescription costs. Those with very high drug costs would receive special coverage.

No one would have to pay more than \$3000 annually out-of-pocket. This might cost \$16 - \$25 billion annually, though this may be the estimated gross cost, not the net cost after subtracting current spending on drugs financed through Medicaid or through private insurance that seniors now buy through medi-gap coverage or obtain through HMOs. This figure may also reflect a partial offset of reduced hospital or physician spending against the gross cost of drugs.

<u>Voluntary drug insurance for seniors.</u> President Clinton has announced such a voluntary approach. Starting in 2002, it would cover the first \$2,000 in drug purchases, with a 50 percent co-payment and a \$24 monthly premium. The cap would rise to \$5,000 by 2008 and the premium would rise to \$44 monthly. This plan is badly flawed in three ways.

- First, because it is voluntary, it would induce those seniors who knew they needed costly
 medications to sign up in disproportionate numbers. This problem is called "adverse
 selection" and is especially serious when prescription drugs are concerned because drug
 spending is typically the most predictable health care cost from year to year.
- Second, it helps many people a little but fails to provide focused help to the people who
 need it the most—those with very costly drug needs. Any targeted drug benefit should focus
 on meeting the needs of people who require expensive medications that they cannot afford.
- Third, it would tend to increase drug spending. That is the least sensible way to ameliorate
 the drug problem. Throwing fuel on the financial fire of drug spending, it would exacerbate
 our spending problem and therefore make it harder to cope with in the future.

Critics of the president's plan consider it "too complex and vague" to pass. As a result, nearly every drug manufacturer's stock price rose immediately after it was announced. 161

Massachusetts Governor Paul Cellucci's administration has also announced a state-sponsored voluntary drug plan for seniors. Low-income seniors would pay no premiums and face a deductible as low as \$750; individuals with incomes above \$12,360 would pay monthly premiums of about \$50 and face \$1,500 deductibles. There would be no ceiling on benefits.

This uncapped, high-deductible benefits plan is an improvement on the president's because it concentrates its help toward lower-income people and also people who require costly medications for a long time. But it still would impose substantial premium and deductible costs before any benefits are available for people just above its "low income" threshold. And this plan also suffers from the problem of adverse selection. The plan would be subsidized to attract seniors who would not require costly medications. It is feared that, without such a subsidy, seniors in greatest need would be most likely to sign up for coverage, raising average cost and therefore average premium. But it does not seem likely that the proposed subsidy will be adequate to prevent adverse selection. And it would be administratively tortuous to try to identify a premium and deductible package that would be optimal in countering adverse selection and also be fairly calibrated to income. Further, an adequate subsidy would be costly to state government. This state plan would also tend to increase spending on drugs.

These efforts are well-intentioned and may serve as short-term stop-gaps. Some might call them only bandages, but bleeding wounds need bandaging. The problems associated with these approaches, though, are clear to everyone, particularly to their sponsors. These approaches increase spending on prescription drugs. They do nothing to control costs. They

do not seem to be durably sustainable. And the voluntary approaches are particularly unlikely to last.

Everyone involved is aware of these difficulties. They feel, though, that spending controls are impossible to legislate, so spending more money is the only path to improved coverage.

The influence of the manufacturers is so high in Washington that they would probably strip any proposed Medicare drug benefit of the teeth to negotiate the very sorts of discounted prices that would make the program affordable. And even if the drug makers were somehow forced to lower prices to Medicare patients, they would respond by raising prices on everyone else. As they constantly remind us, their first duty is to their stockholders.

Also, a seniors-only or program or a program only for people with disabilities would ignore the needs of younger people who cannot afford needed medications.

<u>Negotiate rebate with manufacturers.</u> Because prescription drugs are the fastest growing component of health care spending, some HMOs expect that drugs will soon be their second-biggest cost, behind only physician care and edging past hospitals themselves.¹⁶⁶

Any public dollar we spend on medications is a dollar we cannot spend on education, housing, job training, the environment, infrastructure, criminal justice, or anything else that anyone cares about. And many of those other things also improve health.

The United States of America has the world's costliest health care, at roughly \$4,400 per person this year. That means we already spend enough to finance all the health services that work for everyone who needs them.

As discussed earlier, U.S. prescription drug spending per person was fourth-highest in the world in 1997; it may already be highest. Current prescription drug spending should therefore be adequate to finance all the medications that all Americans need. The challenge facing all of us is to spend this money to achieve that goal. We should not have to spend more money—throw more money at the manufacturers.

Federal legislation could call for all manufacturers to pay a specified percentage rebate. The rebated sums could used to buy prescription drugs at the prices negotiated by the methods described earlier.

The proposed Massachusetts and Vermont state legislation described earlier would seek discounts; it would also empower the state to negotiate with the drug manufacturers to win rebates to squeeze out an estimated \$300 million yearly in Massachusetts alone. That money would be used to buy drugs for people who can't now afford them. Help over three-quarters of the \$300 million would be returned to manufacturers, after paying fair costs for dispensing the medications. In exchange, the manufacturers must provide more medication. But the marginal cost of doing so is tiny, since most of their costs are fixed—for research, testing, and establishing the manufacturing lines. The low marginal cost—the low cost of the *next* pill—makes the manufacturers' failure to make sufficient medications available and affordable to all Americans a tragic mistake. We should not tolerate that any longer.

How much would a rebate and recycling proposal cost the manufacturers? The following estimates are from the proposed Massachusetts legislation. Similar ratios would apply elsewhere.

The proposed Massachusetts rebate program might be seen as a recycling program. It means that greater volumes of medications will be made available by better using existing spending—and without spending new money.

Cost. How much would the rebate program cost the manufacturers? Surprisingly little. In effect, they would be providing more medications—medications that cost them very little to manufacture. Of the rebated \$300 million, most would return to them. The manufacturers would forgo the 26 percent of the \$300 million that would cover the costs of distributing the medications and dispensing them through retail pharmacies. This would be \$78 million. The manufacturers would have to finance the manufacture of the additional capsules, pills, and other medications. The AAMP estimates the marginal cost of manufacturing at five percent of the retail price. This would be \$15 million. Together, these two costs would total \$93 million. But the citizens of Massachusetts would benefit by receiving medications priced at \$300 million (at retail) that they had not previously been able to afford.

Rebate Summary:

Net revenue loss to manufacturers from rebate \$78 million

Net costs of providing additional medications \$15 million

Total financial pain for manufacturers \$ 93 million

Total benefit to patients \$300 million

Alternatively, were this considered unpalatable, public money currently devoted to buying drugs through a state senior pharmacy program or other vehicles could be used to pay some or all of the distribution costs and the dispensing and other retail costs of these medications. That would relieve the manufacturers of this burden. If so, the rebate would cost the manufacturers as little as the \$15 million estimated marginal cost of providing the additional medications.

Manufacturers might claim that they would be forgoing \$300 million in added revenue—the revenue that would be generated if they could have sold the medications that are purchased with the rebated money. But that's hardly likely, since those are drugs that would go to Bay Staters who are unable to afford them today.

Manufacturers' revenue would continue to grow for other reasons—the same reasons that they have grown in recent years.

Overall summary: Discount plus rebate. Factoring in the discount described in the previous section, these are the conservative 1999 estimates of costs to manufacturers and of benefits to patients associated with the Massachusetts proposal.

Lower revenue/higher cost to manufacturers

discount \$223 million¹⁷¹ rebate \$ 93 million

total \$316 million

Benefits to patients

discount \$357 million rebate \$300 million

total \$657 million

Gain to patients / pain to manufacturers: 2.08 / 1.00

This way to address prescription drug cost and coverage problems, which **buys at least twice as much in benefits to patients as it costs manufacturers**, deserves serious consideration—especially given the dearth of affordable alternatives.

Even better, the cost of the discount and the rebate to manufacturers could be much lower than just estimated. If so, the resulting gain-to-pain ratio could be as high as 4:1 or even 6:1. This could happen:

- if the Merrill Lynch estimates of the price elasticity of demand are more accurate than the conservative –0.33 used in the above calculations—and
- if existing senior pharmacy or other public funds are used to pay for the distribution and dispensing costs of drugs dispensed through the rebate program.

Again, the drug companies persist in denouncing any potential constraint on their U.S. revenues or profits. They insist, in practice, that they need all the money they can extract from Americans. But they must be asked: How much profit do they really require? What is the minimum profit they need to finance vital research? And what is their upper limit on their profits, if any?

Negotiate with manufacturers for more drugs for the same dollars. The federal government or a state government might negotiate with each drug company to try to secure an in-kind donation of drugs whose average wholesale price would equal 25 percent of the wholesale price of the medications sold in the state by that company. (Wholesale prices or average manufacturing prices would be used because these are easier to measure in a fair and consistent manner. Retail prices are much more difficult to measure.)

The drugs would be made available through ordinary retail channels when ordered by physicians for patients deemed unable to afford those drugs.

Dispensing fees might be paid with public money, probably from the senior pharmacy programs, where they exist, or from new public sources. Appropriating the needed funds might seem attractive, since they leverage so much in the way of valuable medications. The retail pharmacies might be effective allies since they would see a considerable rise in dispensing fees. (As discussed earlier, these might total over \$3 billion annually.)

This approach might be seen as a simpler, in-kind equivalent of the rebate provision of the Massachusetts and Vermont bills. It might also be seen as a streamlining of the drug companies' own private gift programs—most of which are among the more bureaucratic and wasteful acts of generosity in the world today.

Again, the out-of-pocket cost to the manufacturers would be vanishingly small, since the manufacturers' marginal manufacturing and distribution costs are truly tiny.

If retail drug sales in the U.S. reach \$100 billion this year and manufacturers' shares hold steady at 74 percent, that means a wholesale value of about \$74 billion. One-quarter of that would be \$18.5 billion, measured at wholesale prices. The retail value of these medications would be approximately \$25 billion.

If the marginal cost of manufacturing is only 5 percent of retail, the out-of-pocket costs to the manufacturers—the cost of providing medications with a retail value totaling \$25 billion— would be only \$1.25 billion. That is less than one percent—just 0.84 percent— of the \$148,699,000,000 total revenue of the top twelve U.S. manufacturers alone in 1998.¹⁷³

It is possible to demonstrate the approximate financial effect of such a policy, had it been in effect in 1998. If these twelve manufacturers had borne the entire burden of expending the \$1.25 billion to finance the manufacturing cost of providing 25 percent more medications to Americans, their combined profit would have fallen from \$26,178,000,000 to \$24,928,000,000. That would have meant a drop in profit as a percentage of revenue from 17.6 percent to 16.8 percent. Pharmaceutical industry profits measured by return on revenue would have remained in first place among U.S. industries, still well above the second-place 13.2 percent of revenue garnered by commercial banks.¹⁷⁴

Shouldering the incremental cost of manufacturing more medications need not neutralize even one dollar of drug company profits. Alternatives are readily at hand. For example:

- As noted earlier, the combined 1997 total compensation of the top ten drug company CEOs totaled \$229 million.¹⁷⁵ That sum alone would finance 18.3 percent of this \$1.25 billion cost of manufacturing additional medications for Americans.
- The drug industry's direct-to-patient advertising in the U.S. was estimated to have reached \$1.5 billion for the twelve months through March 1999. We consider this wasteful spending. That sum is more than adequate to finance the manufacturing cost of a 25 percent increase in the volume of medications made available to Americans. It would be far better for patients if that sum could be devoted to financing the very low manufacturing costs of the proposed in-kind donation of drugs.
- The pharmaceutical industry's heavy spending on lobbying is another logical place to seek savings. To lobby Congress and the president in 1997-98, drug makers reportedly spent \$138 million, the most of any industry.¹⁷⁸

- In addition, the industry is reportedly planning a \$30 million advertising campaign aimed at mobilizing public opinion against the president's Medicare prescription drug benefit proposal that is now before Congress.¹⁷⁹ Even that more modest sum could be put to far better use. For example, \$30 million equals the 1999 state appropriation for the Massachusetts senior pharmacy assistance program— but its impact could be much greater; if many drugs' real cost is about five percent of their undiscounted retail prices, \$30 million could provide people in need with medications retail priced at fully \$600 million.
- And drug makers should act to maintain revenues and profits by starting to ask other wealthy nations to pay their fair share of pharmaceutical research costs and profits.

Nationally, drugs valued at \$25 billion at retail would have an average wholesale price of about \$18.5 billion (since the manufacturers retain about 74 percent of the retail dollar). This \$18.5 billion is very close to the 1999 estimate of \$16.2 billion as the *minimum* amount Americans over-pay for prescription drugs—measured by the 1991 differential between U.S. and Canadian wholesale prices. (Please refer to Exhibit 4, on the various estimates of the extra sums that Americans spend on prescription drugs.)

The comparable values in a state like Massachusetts would be \$463 million in free medications, measured at average wholesale prices (one-quarter of 74 percent of \$2.5 billion)—or \$625 million measured at retail prices—costing the manufacturers only \$31 million out-of-pocket (5 percent of \$625 million).

The manufacturers would claim that they would be forgoing \$18.5 billion in added revenue. But that's hardly likely, since the extra medications made available under this approach are drugs that are not being sold today. Therefore, they would be drugs provided to Americans who are today unable to afford needed medications.

And again, manufacturers' revenue would continue to grow for other reasons—the same reasons that they have grown in recent years.

3. Elements of Durable Reform

As discussed earlier, most of the interventions included in the four-part classification are designed to win short-term relief by addressing the immediate problems of high prices and inability to afford needed drugs. They are intended to put our house in order, so we can prepare to deal with long-term prescription drug problems.

The interventions designed to win long-term reforms—such as targeting drug development in more affordable directions and setting research priorities with patient need in mind, negotiating an international prescription drug price treaty, ascertaining fair rates of return to manufacturers (commensurate with real risk), improving physician prescribing by securing better evidence on benefits and costs of medications, outlawing direct-to-patient advertising, and improving patients' own use of drugs—are essential elements of reform.

Several types of long-term reforms are required:

<u>Drug development</u>. Whenever possible, research into new medications should give special emphasis to drugs that are both effective and affordable. This means trying to anticipate and

gauge the costs and efficacy of new medications as early in the development process as possible. *Fair levels of profit should be negotiated* between payors and manufacturers. *Fair profit would be the level needed to retain and attract capital necessary to finance necessary research.* Appropriate risk should be appropriately rewarded. It may well be useful to invest substantially more public money to support the research on which it would be hard to earn a private return—the riskiest research, the most basic research, or research into medications to treat low-prevalence diseases and diseases of poor populations, ¹⁸⁰ for example.

Drug pricing. The broad outlines of fair international drug pricing are clear. Wealthy nations all should pay the same prices for medications, and these prices should be sufficient to finance the overwhelming share of the drug manufacturers' own legitimate research, manufacturing, and other costs. Moderate-income nations should pay prices that cover the incremental costs of the medications they use, plus a reasonable contribution toward fixed costs. Poor nations should receive needed medications at no more than symbolic prices. Many nations and the pharmaceutical industry have been conferring for years on "harmonization"—an effort to coordinate policies internationally on issues such as drug quality standards. A harmonization effort is required on drug pricing as well, to negotiate a peace treaty on prescription drug prices, ensuring that wealthy nations pay their fair share and that needed drugs are available to all. If the Clinton administration can turn to the World Trade Organization on behalf of United Fruit and Dole, to help them secure a share of a \$200 million banana market, it seems appropriate also to involve the WTO in helping secure fair international prices for vital medications.

<u>Drug prescribing</u>. Today, most manufacturers' interest in their medications subsides speedily after the drug is prescribed and purchased. But from society's viewpoint, appropriate drug use saves lives and costs less than inappropriate drug use. Physicians need accurate information on which drugs are helpful to which patients. To help them spend inevitably limited resources carefully, they also need data on the cost-effectiveness of various medications. Given how busy physicians are, all educational materials about drug use must be objective. *All educational materials—and all the research on costs and effectiveness of medications that is required to inform good education—must therefore be financed either publicly or by independent entities.* Advertising and marketing by manufacturers are not legitimate methods of disseminating information. Also, FDA tracking of adverse reactions to medications must be expanded, as it provides evidence essential to using drugs appropriately.

<u>Drug use</u>. Physicians and pharmacists must be paid appropriately to take the time needed to educate patients about appropriate use of their prescribed drugs. No financial barriers should be permitted to block patients from using the right drugs at the right times.

Now is the time to wrestle seriously with this nation's real prescription drug problems, and to gradually change course in a durably affordable and decent direction. If we wait too long, and if we continue to throw more money into financing business as usual, it will become harder over time to cure drug makers of their addiction to high prices.

E. CONCLUSIONS

We spend enough on prescription drugs already to buy all the medications that work for all the Americans who need them. It is frustrating and sad that most proposals to address the problems of prescription drug costs and coverage fall so short of that goal. Some may say that reaching that goal is unrealistic. In reality, further suffering is unacceptable, and higher spending is unaffordable. Instead, today's high drug spending makes the prescription drug affordability problem easy to solve.

1. Relief

It is wrong to allow any American to continue to suffer for lack of needed medications. It is unaffordable and unnecessary to increase total spending on prescription drugs. But the alternative is clear.

By winning lower prices and by obtaining greater volumes of prescription drugs from manufacturers, Americans can secure the medications we require without increasing total spending above the levels we pay this year—or those projected for the years immediately ahead.

Prices must be lowered so Americans pay only our fair share of the cost of developing new drugs and protecting manufacturers' profits at levels high enough to sustain needed research into new and effective medications. In exchange for the substantial sums spent on medications nationally, all manufacturers must agree to provide needed volumes of drugs to all Americans.

These two steps will not give us a perfect system for buying drugs and making them affordable for all Americans. But they will provide a fair measure of immediate relief. This breathing space must be used to devise ways to make needed medications affordable for all by reforming American methods of developing, financing, prescribing, and using prescription drugs.

2. Reform

Americans can secure effective and durably affordable medications for decades to come. As discussed earlier, steps should be taken in at least four areas to reach this objective: drug development, drug pricing and profits, drug prescribing by physicians, and drug use by patients. These steps must be taken in ways that satisfy the legitimate needs of the world's drug industry and all other stakeholders.

Public intervention and public-private negotiation will be required to address these needs. *The future trajectory of prescription drug policy and financing should be planned cooperatively among all stakeholders*: patients who could be helped by effective new medications; insurors and ultimate payors (public and private) who finance drugs; physicians who prescribe drugs; hospitals, physicians, nursing homes, and other caregivers who compete with the drug industry for their fair shares of an increasingly finite health dollar; and the drug industry itself.

3. Federal or state action?

Winning affordable and effective medications for all Americans requires complementary federal and state efforts.

Debates over proposed federal legislation can help inform more Americans about the nature, causes, and possible solutions to our prescription drug problems. Debates in Washington can help inspire and craft state legislative initiatives. And the chances of passing a law in one of 50 states are substantially greater.

Marshaling the entire nation's bargaining power through federal action would win lower drug prices for all Americans and also mobilize more money to buy medications for people who cannot afford them. But the federal government is paralyzed generally in many areas. It is hard to craft one prescription drug policy that satisfies the needs and preferences of rich states and poor, liberal states and conservative, states with higher and lower drug spending, and states with more or fewer uninsured people. Perhaps most important, it will be easier for the federal government to act after states provide more evidence about what works. Reforms in the states—the laboratories of democracy—will help to uncover that evidence.

Experimentation is needed. How else can we learn what works best? Experimentation is easier at the state level for at least three reasons. First, the stakes are not as dramatic as they would be nationally. Second, states will find it easier to tailor solutions to their circumstances. Third, many state legislators are so secure politically that they have fewer worries that drug manufacturers' money might finance their opponents.

Still, many new programs don't work as well as hoped and require fine-tuning or even substantial revision. But there is no reason to expect that they would be risky for patients. And major league baseball players enter the Hall of Fame with lifetime batting averages of .333, meaning that hits were only one-third of at-bats. Well-planned experiments might enjoy a better batting average. Even so, they would only be tolerable politically if we came to accept frequent failure as the price of progress. Today, we understand this in the private sector but tend to condemn it as waste in the public sector.

If Congress does not act soon, individual states should therefore consider acting on their own. As noted earlier, states have surprising purchasing power. As shown in Exhibit 14, California's health spending is greater than France's, New York's is greater than Italy's or the U.K.'s, Texas's is greater than Canada's, and even Massachusetts's is about that of Australia or the Netherlands. Multi-state compacts would substantially enhance states' leverage in the drug marketplace.

4. Making the Choices—Addressing All Legitimate Concerns

Today, Americans pay high drug prices and many cannot afford the medications they need. State and federal governments have faced—and are responding to—growing public pressure to address these problems.

At the same time, the drug makers are worried about any threats to their ability to extract high prices and profits from American patients—dollars adequate to pay high returns on stockholder equity and also to finance research that will engender new profitable drugs.

Americans must choose among three responses: continuing to suffer for lack of needed medications, paying more for them, and winning more medications without spending more. The very low marginal or incremental costs of most medications should allow the drug makers to supply the additional volumes of drugs that Americans require without incurring large financial penalties. Profit margins may drop slightly, but that seems fair. Their profits have been extraordinarily high, year after year, and therefore taking both risk and research costs into account.

As Americans, we do not have to

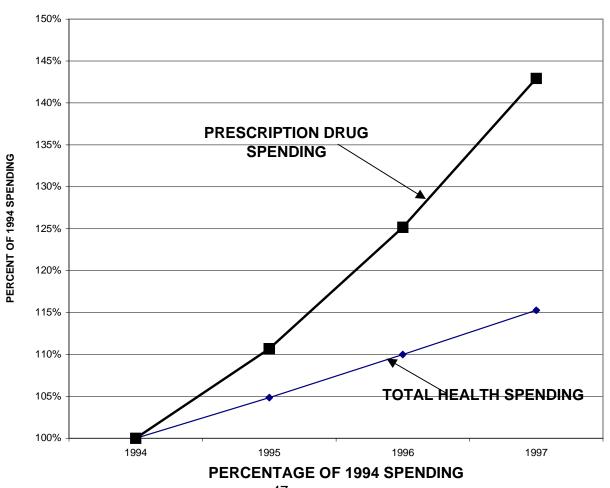
- torture ourselves.
- sacrifice private or public spending required to address other pressing needs, or
- squeeze the manufacturers harshly

in order to win affordable and effective medications for all patients who require them.

Since U.S. prescription drug spending per person this year will probably be highest in the world, it is adequate, by all international standards, to finance all the drugs that all Americans require. That should make the task of winning affordable medications for all the easiest job facing our nation.

EXHIBITS Exhibit 1

TOTAL HEALTH AND PRESCRIPTION DRUG SPENDING, U.S., AS PERCENT OF 1994 SPENDING



PHARMACEUTICAL SPENDING PER CAPITA, WEALTHY NATIONS, 1997

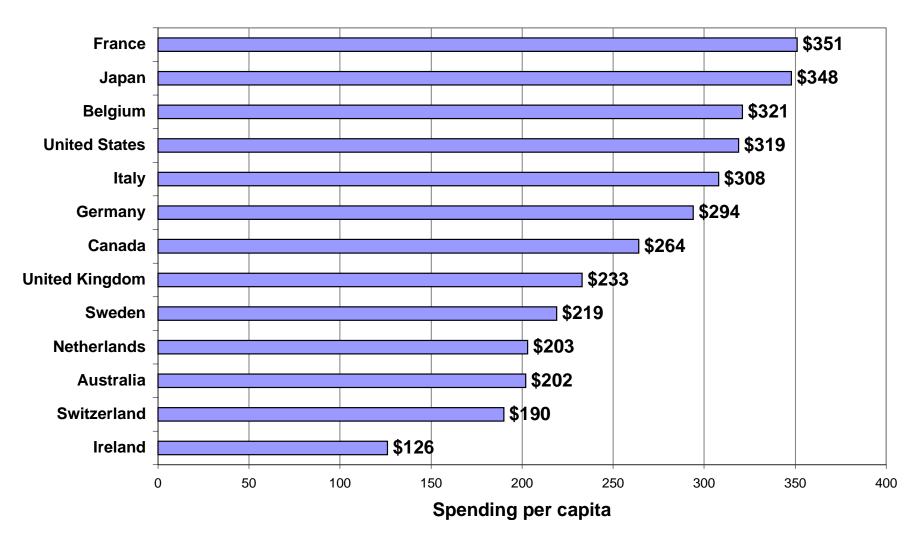


Exhibit 2

THE WORLD'S PHARMACEUTICAL MARKET, 1996

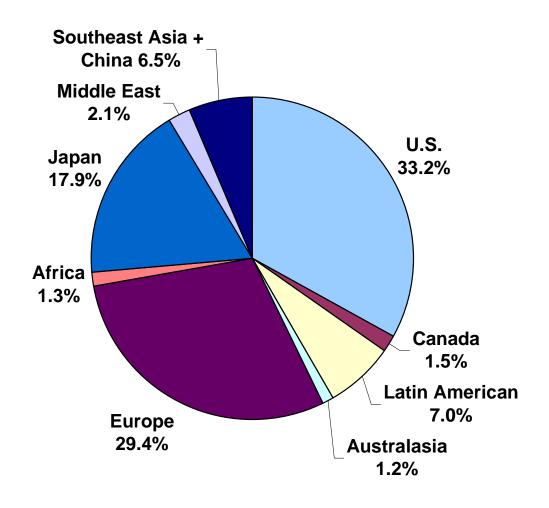


Exhibit 3

Exhibit 4

ESTIMATED U.S. WHOLESALE PRESCRIPTION DRUG SPENDING USING PRICES PAID BY SEVERAL NATIONS, \$ BILLIONS, 1999

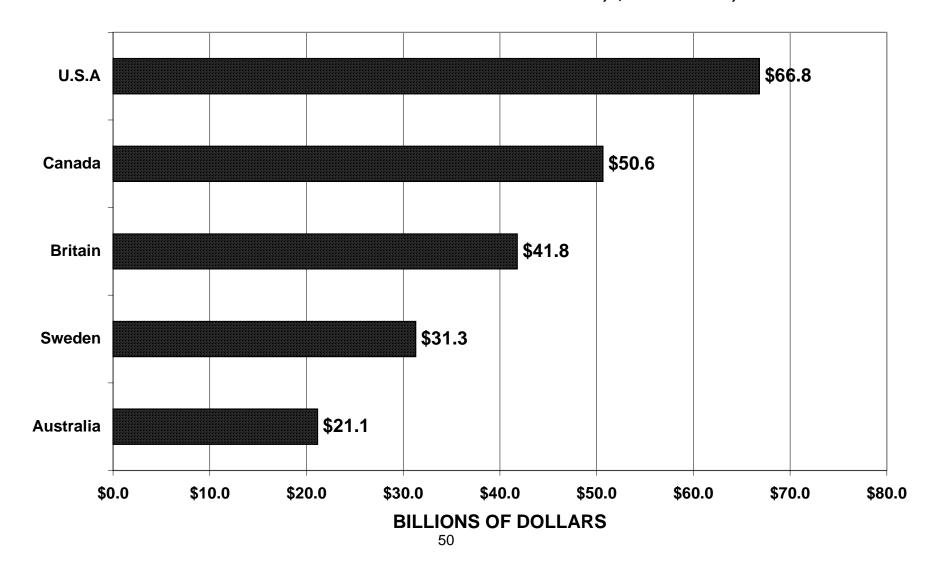


Exhibit 5

FOREIGN AID: WHAT CONGRESS VOTES VERSUS WHAT THE DRUG COMPANIES EXTRACT, CONSERVATIVE ESTIMATES, 1999 (\$ BILLIONS)

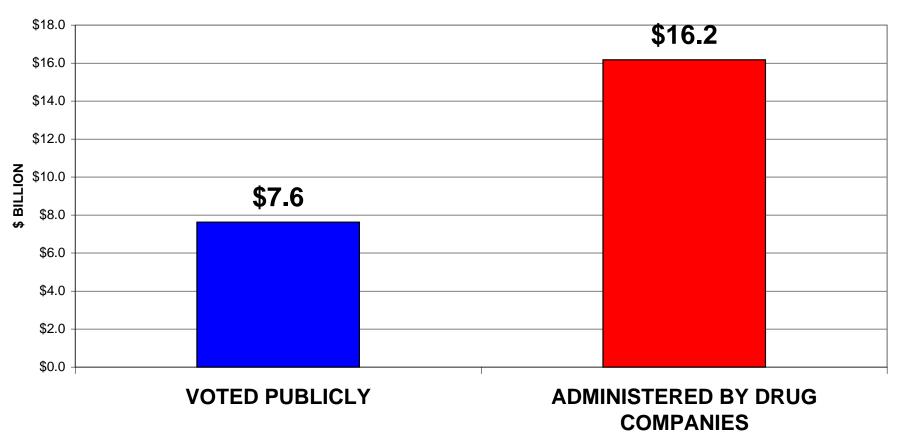


Exhibit 6

RETAIL PRESCRIPTION DRUGS AS PERCENT OF U.S. HEALTH SPENDING, 1960 - 1997

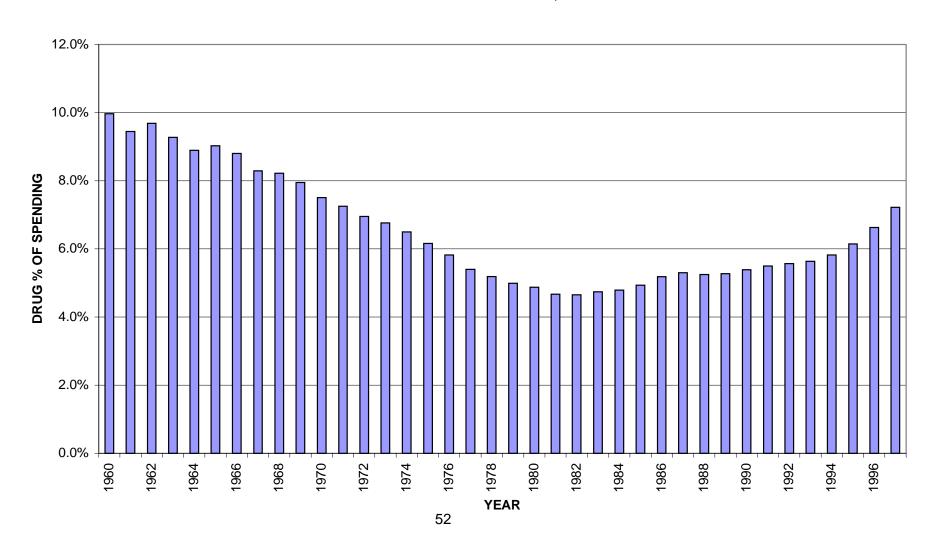


Exhibit 7

PRESCRIPTION DRUG SPENDING AS A SHARE OF GROSS DOMESTIC PRODUCT, 1997

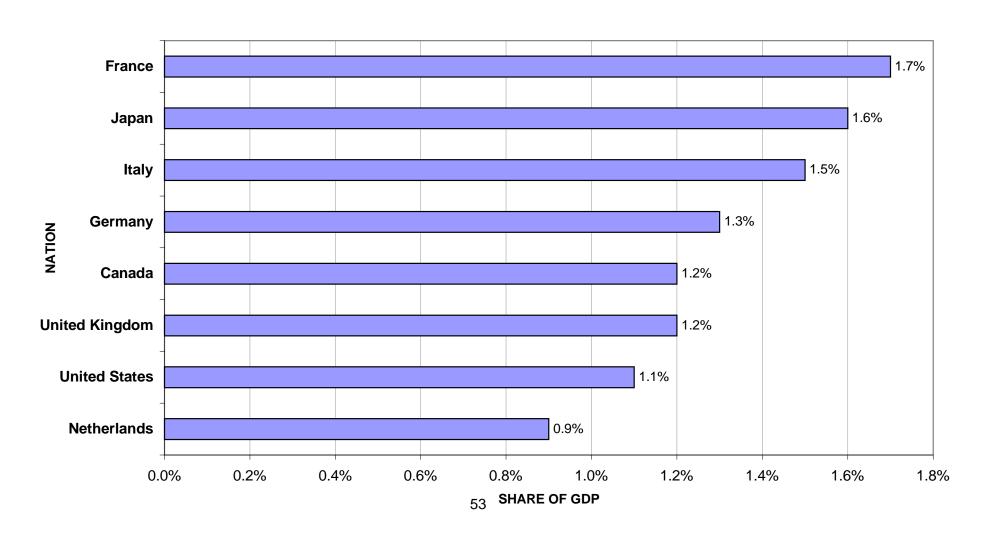


Exhibit 8

PRESCRIPTION DRUG RESEARCH AS A SHARE OF NATIONAL HEALTH SPENDING, 1990 - 1994 AVERAGE

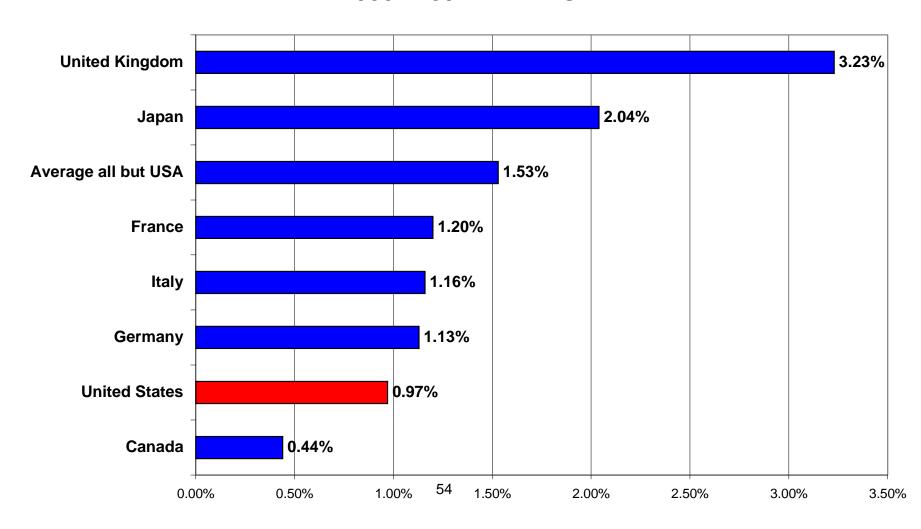


Exhibit 9

PHARMACEUTICAL AND ALL-INDUSTRY RETURNS ON EQUITY, 1970 - 1998

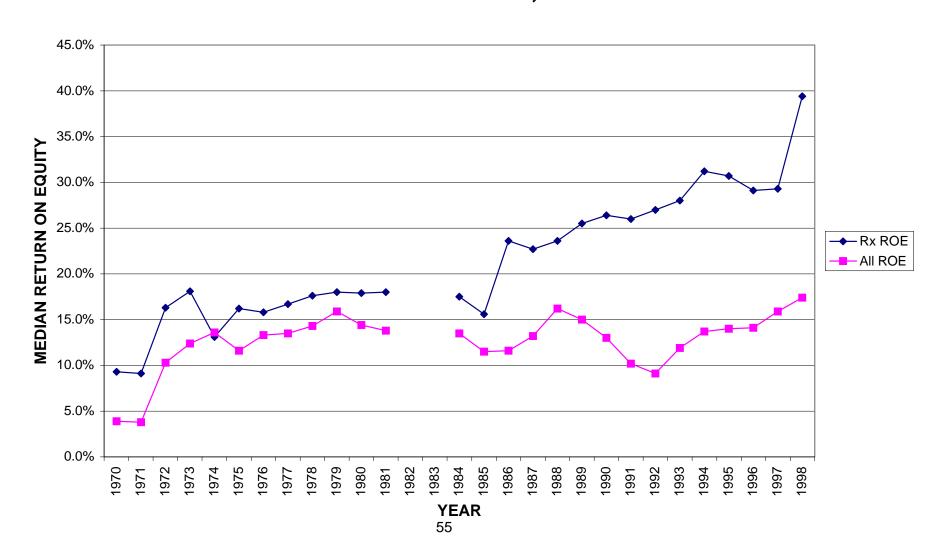


Exhibit 10

DRUG INDUSTRY MEDIAN RETURN ON EQUITY AS PCT. OF ALL-INDUSTRY MEDIAN, 1970 - 1998

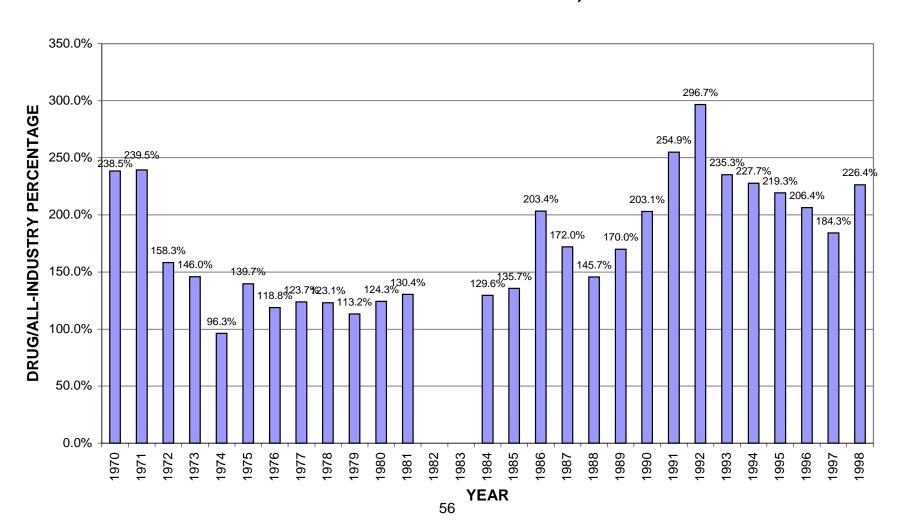
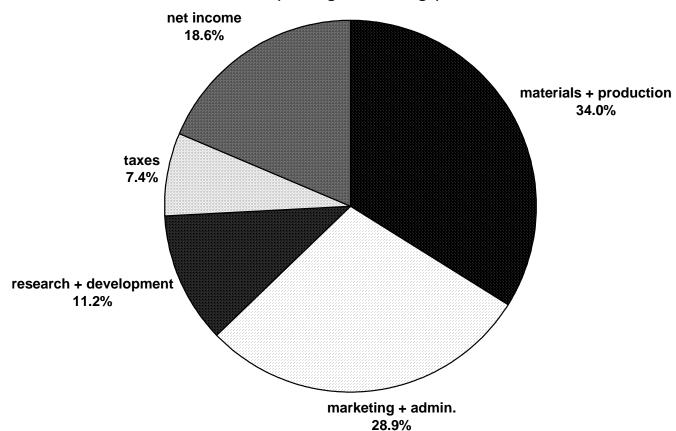


Exhibit 11

WHERE MERCK'S AND PFIZER'S REVENUE WENT, 1997

(Unweighted Average)



INCOME INEQUALITY, OECD NATIONS WHOSE PER CAPITA GDP EXCEEDED \$15,000, 1982 -1994

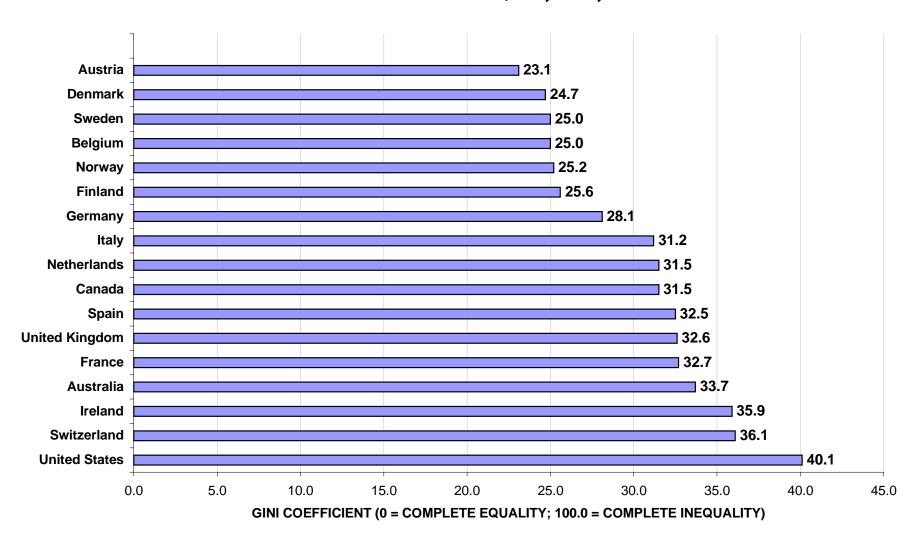


Exhibit 13

COMPONENTS OF THE PRICE OF THE AVERAGE PRESCRIPTION (\$38.64), CHAIN DRUGS STORES, 1998

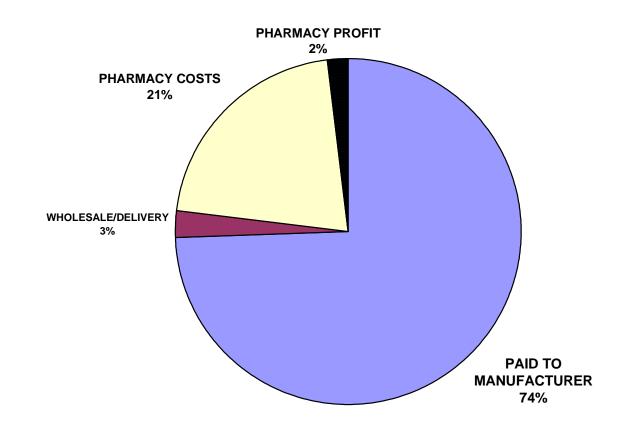
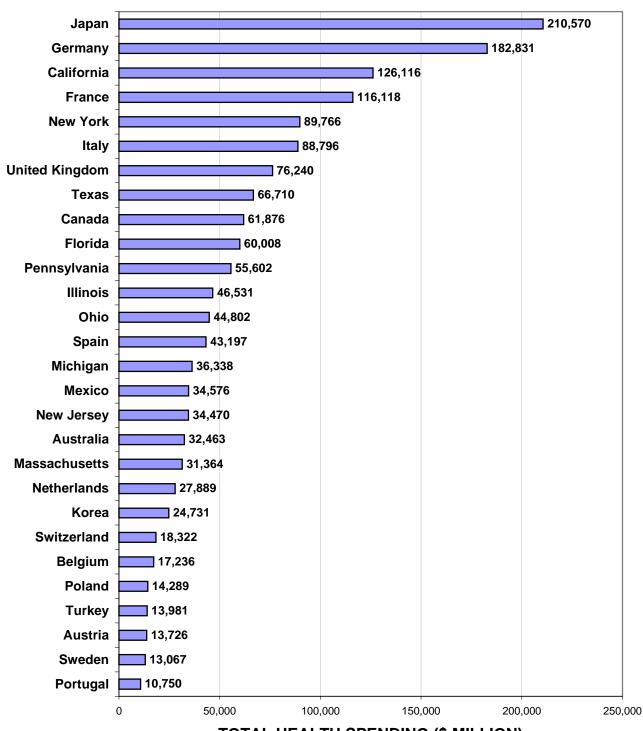


Exhibit 14
TOTAL HEALTH SPENDING, O.E.C.D. NATIONS
AND U.S. STATES, 1996



TOTAL HEALTH SPENDING (\$ MILLION)

AAMP REPORTS

To obtain copies of other reports, please telephone (617) 638-5042, or email dsocolar@bu.edu or asager@bu.edu. Here is a list of selected reports, testimony, and articles by Project principals:

Winning Affordable Prescription Drugs for All Bay Staters, 8 June 1999.

"Massachusetts Should Identify and Stabilize All the Hospitals Needed to Protect the Health of the People," testimony to the Massachusetts Health Care Committee, 20 May 1999.

"Affordable Medications for Vermont," testimony on An Act Relating to the Vermont Prescription Drug Pricing and Consumer Protection Program, 28 April 1999.

"Testimony on Universal Health Care," testimony to the Massachusetts Health Care Committee, 27 April 1999.

"Uninsured and Under-Insured in Massachusetts," testimony to the Massachusetts Health Care Committee, 27 April 1999.

"Getting More for Our Health Care Dollar," testimony to the Massachusetts Insurance Committee, 6 April 1999.

Pharmacy Freedom of Choice Legislation for Rhode Island, 24 March 1999.

"A fairer prescription drug plan," Boston Globe op.ed., 26 January 1999.

"What Are the Forces Threatening Hale Hospital, and How Can Haverhill Respond?" 29 January 1998

"Do Rx drugs cost too much? The market needs a peace treaty," *Business and Health*, October 1997.

"760,000 Massachusetts Residents Lacked Health Insurance in 1996 – the Largest Number Recorded," September 1997.

Before It's Too Late: Why Hospital Closings Are Becoming a Problem, Not a Solution-Early Findings from the Massachusetts Hospital Reconfiguration Study, 2nd edition, 2 June 1997.

Alan Sager and Deborah Socolar, *Pharmacy Closings in Massachusetts, 1980-1995*, 15 May 1997.

"Imprudent and impatient: Are hospitals closing too fast and for insufficient reason?" *Boston Sunday Globe*, Focus section, 27 April 1997.

"A 10-Step Plan for Healthy HMOs," Boston Globe, 10 September 1996.

"Health Care for Boston," in Joseph R. Baressi and Joseph S. Slavet, eds., *Boston Update '94*, John W. McCormack Institute of Public Affairs, University of Massachusetts, Boston, April 1994.

"Public not served by merger of MGH, Brigham," *Boston Business Journal*, 14-20 January 1994.

"Nine Lessons from the Failure of the 1988 Massachusetts Universal Health Care Law," 26 October 1993.

"We Don't Have to Keep Paying Through the Nose to Get Vital Prescribed Medications into Our Bodies," 21 June 1993, written testimony for the Subcommittee on Health, Committee on Ways and Means, U.S. House of Representatives.

"Competing to Death: California's High-risk System," *Journal of American Health Policy*, March-April 1992.

The World's Most Expensive Hospitals: One-fifth of Massachusetts Hospital Costs Appear_Unjustified, 1 February 1991.

Promise and Performance: "An Act to Make Health Security Available to All Citizens of the Commonwealth and Improve Hospital Financing" (Chapter 23 of 1988), 9 April 1989.

* * *

Also note the following co-authored report and article:

"More Care, Less Cost," *Boston Globe,* Sunday Focus section article, co-authored with Solutions for Progress, 25 April 1999.

Universal Comprehensive Coverage: Modeling the Cost of Health Care Reform in Massachusetts, report to the Massachusetts Medical Society, co-authored with Solutions for Progress, December 1998.

Acknowledgement

The Access and Affordability Monitoring Project gratefully acknowledges financial support from The Boston Foundation, The Boston Globe Foundation, New England Financial, and the Erna Yaffe Foundation

NOTES

¹ Katharine Levit, Cathy Cowan, Bradley Braden, and others, "National Health Expenditures in 1997: More Slow Growth," *Health Affairs*, Vol. 17, No. 6 (November – December 1998), pp. 99-110, calculated from data in Exhibit 1.

² Alan Sager, "All the Money We Need," Presentation to the Committee on Federal Government Affairs, American Academy of Pediatrics, Ritz-Carlton Hotel, Arlington, Virginia, 24 January 1999.

³ IMS Health data reported in "Prescription-drug Sales Are Expected to Climb 43% in the U.S. by 2002," Dow Jones, 8 June 1999.

⁴ U.S. Census Bureau, "Health Insurance Coverage: 1997," 28 September 1999, www.census.gov/hhes/hlthins/hlthins97.

⁵ Health Care Financing Administration, Office of Strategic Planning, data from the Medicare Current Beneficiary Survey, cited in Margaret Davis, John Poisal, George Chulis, and others, "Prescription Drug Coverage, Utilization, and Spending among Medicare Beneficiaries," *Health Affairs*, Vol. 18, No. 1 (January – February 1999), pp. 231-243, exhibit 1.

⁶ Personal communication reporting on 1993 survey by the Health Insurance Association of America, Al Minor, HIAA Research Department, 18 September 1995.

⁷ Some 165.1 million Americans had employment-based private health insurance in 1997 (U.S. Census Bureau, "Health Insurance Coverage: 1997," 28 September 1999, www.census.gov/hhes/hlthins/hlthins97, Table 1); 7 percent of this is 11.6 million people.

⁸ We are inclined to increase this estimate to 70 million for several reasons. First, we expect that the number of entirely uninsured Americans has continued its steady rise through 1999. Second, we expect that the number of Medicare recipients lacking coverage for prescription drugs has risen owing to the rising prices of traditional Medicare supplementary insurance that includes prescription drugs, to the exodus of many health maintenance organizations from the Medicare market during 1999, and to elimination of prescription drug benefits by many of the HMOs that continue to participate in Medicare. Third, we believe that employers offering private health insurance have been slightly more likely to drop prescription drug coverage owing to its rising price.

⁹ We use a 1 July 1999 population estimate of 272.9 million Americans. This was derived simply by taking the 1998 population and increasing it at the same 0.9542247 percent rise that is estimated to have taken place from 1 July 1997 to 1 July 1998. See Population Estimates Program, Population Division, U.S. Census Bureau, "State Population Estimates: Annual Time Series, July 1, 1990 to July 1, 1998, ST-98-3.

¹⁰ Alex Pham, "Report: Poor Use Fewer Prescription Drugs," *Boston Globe, 4* March 1999, summarizing findings of Stephen B. Soumerai and Dennis Ross-Degnan, "Inadequate Prescription-drug Coverage for Medicare Enrollees—A Call to Action," *New England Journal of Medicine*, Vol. 340, No. 9 (4 March 1999), pp. 722-728.

¹¹ For example, see Alex Pham, "Harvard to Alter How Members Pay for Pills: Copayments could reach \$30 or More," *Boston Globe*, 12 June 1999.

¹² These are our estimates; they rest on reports of actual 1997 retail prescription drug spending in Katharine Levit, Cathy Cowan, Bradley Braden, and others, "National Health Expenditures in 1997: More Slow Growth," *Health Affairs*, Vol. 17, No. 6 (Nov.-Dec. 1998), pp. 99-110, Exhibit 1. We raised these by the 1996-1997 rate of increase of 14.2 percent annually.

¹³ In 1997, the most recent year for which data are available, Pharmaceutical Research and Manufacturers of America reported total sales for human use in the U.S. market, net of discounts and rebates, of \$65.9 billion. See *The PhRMA Industry Profile, 1999, Appendix Table 15, in* www.phrma.org/publications/industry/profile99. We assumed, as discussed elsewhere, that this figure for actual manufacturers' revenue comprised 74 percent of retail sales, so we divided it by 0.74 to reach estimated actual drug costs to patients. This assumes that hospital and nursing home mark-ups (or effective prices charged to patients or their third party payors) were not different from retail mark-ups. In 1997, retail prescription drug spending reported by Levit and others was 88.6 percent of the total drug spending estimated by this method. We applied this ratio to estimated 1999 retail prescription drug spending in order to estimate 1999 total drug spending.

¹⁴ This made it \$13 (3.9 percent) below our own estimates for 1997 (described in the previous notes).

¹⁵ Organization for Economic Cooperation and Development, *OECD Health Data, 1998*, reported by Pharmaceutical Research and Manufacturers Association, 1999, www.phrma.org/publications/industry/profile99/figures99/7-7.html.

¹⁶ And Japanese spending may be inappropriately inflated because physicians dispense drugs at a profit.

¹⁷ IMS expects compound growth rates of 9.8 percent annually in North America between 1998 and 2002. The overall European average is expected to be only 5.8 percent. And growth in Germany, France, and Italy, for example, is expected to be even lower owing to price controls. See IMS, "Five Year Forecast of the Global Pharmaceutical Markets: Forecast Growth – North America, Europe, and South East Asia," *Global Pharmaceutical Market Forecasts*, www.ims-global.com/insight/report/global/.

¹⁸ Katharine Levit, Cathy Cowan, Bradley Braden, and others, "National Health Expenditures in 1997: More Slow Growth," *Health Affairs*, Vol. 17, No. 6 (November – December 1998), p. 99-110, exhibit 1.

¹⁹ IMS Health data reported in "Prescription-drug Sales Are Expected to Climb 43% in the U.S. by 2002," Dow Jones, 8 June 1999.

It is also worth noting that a recent analysis by U.S. Senator Byron Dorgan's staff of the *retail* prices of a dozen common drugs sold both in the U.S. and Canada found that the U.S. retail prices ranged from 126 percent of the Canadian price up to 380 percent of the Canadian price, with the median ratio 162 percent. "Dorgan Bill Would Give U.S. Consumers Access to Lower Priced Prescription Drugs from Abroad," press release, 9 June 1999.

²⁵ See, for example, U.S. General Accounting Office, *Prescription Drugs: Companies Typically Charge More in the United States than in Canada*, Washington: The Office, September 1992, GAO/HRD-92-110; U.S. General Accounting Office, *Prescription Drugs: Companies Typically Charge More in the United States than in the United Kingdom*, Washington: The Office, January 1994, GAO/HEHS-94-29; U.S. General Accounting Office, *Prescription Drugs: Spending Controls in Four European Countries*, Washington: The Office, May 1994, GAO/HEHS-94-30; U.S. General Accounting Office, *German Health Reforms: Changes Result in Lower Health Costs in 1993*, Washington: The Office, December 1994, GAO/HEHS-95-27.

These estimates all rest on comparisons of the manufacturers' prices— also called factory prices (the prices that manufacturers charge wholesalers)— charged for the same drug, in the same form and dose, in different countries. The underlying data on the price disparities the above U.S. General Accounting Office studies and, for Australia, from analysis by the Access and Affordability Monitoring Project. For Canada, the price comparison was for a market-basket of 121 prescription drugs on 1 May 1991. For the U.K., the market-basket included 77 prescription drugs, in May

²⁰ This is sometimes disputed by drug manufacturers and others. Some claim that the comparison depends in part on which market basket of drugs is considered, or on which method is used to compare prices among nations. Still, Danzon's comprehensive analysis found higher U.S. prescription drug prices by almost all measures. See Patricia Danzon, "The Uses and Abuses of International Price Comparisons," in Robert B. Helms, ed., *Competitive Strategies in the Pharmaceutical Industry*, Washington: American Enterprise Institute Press, 1996, chapter 5, pp. 85-106;

²¹ PhRMA Industry Profile, 1998, citing IMS Health data, 1998.

²² Estes Kefauver, *In a Few Hands: Monopoly Power in America,* New York: Pantheon, 1965, pp. 34-35.

²³ Price data for 1991 from U.S. General Accounting Office, *Prescription Drugs: Companies Typically Charge More in the United States than in Canada,* Washington: The Office, September 1992, GAO/HRD-92-110.

²⁴ Data collected and reported by the Canadian government. Patented Medicine Prices Review Board, *Trends in Patented Drug Prices*, Study Series S-9811, Ottawa: The Board, September 1998, p. 15, http://www.pmprb-cepmb.gc.ca/rm-pat-e.pdf
The report states, "The analysis was done by tracking annual domestic price changes in local currency of each country." Prescription drug prices began falling noticeably in Canada after 1994, when the government adopted a new goal—that the manufacturers' average prices in Canada should be no higher than the median of international prices.

1992. For Sweden, the median price ratio for 20 prescription drugs is employed, and for Australia, the 1992 median price ratio is used, from a sample of 29 drugs (which were also included in the GAO's British and Canadian market-baskets).

²⁶ Larry Nowels, "Appropriations for FY 1999: Foreign Operations, Export Financing, and Related Programs," Congressional Research Service Report for Congress, 2 November 1998, Table 3.

²⁷ For example, "A study by Harvard University Professor Thomas McLaughlin, Sc.D., found that prescription drugs approved in the U.S. in 1990 and 1991 were priced comparably in the U.S., U.K., Germany and Canada in 1993," PhRMA, "Prescription Drug Prices and Profits," Facts and Figures Backgrounder, www.phrma.org/facts/bkgrdnr/prices.html.

²⁸ As discussed later in this report, parallel importing, as practiced in the European Economic Community, allows a member nation to import a drug at a low price from any other member nation that has won such a price.

²⁹ PhRMA, "The Market Is Working," <u>www.phrma.org/issues/market.html.</u>

³⁰ United States General Accounting Office, *Prescription Drugs: Spending Controls in Four European Countries*, Washington: The Office, May 1994, Gao/HEHS-94-30, p. 3.

³¹ Elyse Tanouye and Philip Connors, "New Price Data on Prescriptions Show Big Hikes for Many Drugs," *Wall Street Journal*, 29 June 1999.

³² Pharmaceutical Research and Manufacturers of America, *Industry Profile 1998*, Figure 4-11, www.phrma.org/publications/industry/profile99/fugures99/4-11.html.

³³ Bureau of Labor Statistics, Consumer Price Index, All Urban Consumers, www.bls.gov/sahome.html.

³⁴ Alice Ann Love, "Consumer Prices Flat in May," Associated Press DataStream, 16 June 1999.

³⁵ See, for example, "Some on Border Find Cheaper Rx in Canada, Mexico," Associated Press, 8 July 1999; "Sanders Introduces `Free Trade' Bill for Prescription Drugs," Press Release, www.house.gov/bernie/press/1999/05-20-99.html; and WCCO radio news, "Seniors Go North of Boarder for Lower-Cost Drugs," 8 May 1996, http://channel9000.com/news/stories/news-960508-172934.html.

³⁶ Patented Medicine Prices Review Board, *Trends in Patented Drug Prices*, Study Series S-9811, Ottawa: The Board, September 1998, p. 14, Table 5, http://www.pmprbcepmb.gc.ca/rm-pat-e.pdf

³⁷ PhRMA, "Prescription Drug Prices and Profits," Facts and Figures Backgrounder, www.phrma.org/facts/bkgrdnr/prices.html.

³⁸ PhRMA, "Prescription Drug Prices and Profits," Facts and Figures Backgrounder, www.phrma.org/facts/bkgrdnr/prices.html.

³⁹ Pharmaceutical Research and Manufacturers of America, "International Price Comparisons," Industry Issue Brief, 1994. See also Alan Sager and Deborah Socolar, "Do Rx Drugs Cost Too Much? The Market Needs a Peace Treaty," *Business and Health*, Vol. 15, No. 10 (October 1997), pp. 51-53. For a similar PhRMA concession, see Pharmaceutical Research and Manufacturers of America, "Prescription Drug Prices and Profits," PhRMA Facts and Figures, p. 5, www.phrma.org/ facts/bkgrnder/prices/html.

⁴⁰ Pharmaceutical Research and Manufacturers of America, "International Price Comparisons," Industry Issue Brief, 1994.

⁴¹ PhRMA reports a trade balance of \$1,010 million on exports of \$6,554 million in 1995. PhRMA, *Industry Profile, 1996*, "U.S. Balance of Trade in Medicinal Products," Figure 8-2, www.phrma.org/archive/profile/figures/8-2.html.

⁴² Calculated from Office of the Actuary, Health Care Financing Administration, "1997 Health Expenditures," www.hcfa.gov/stats/nhe-oact/nhe.htm.

⁴³ This reflects the estimate that current retail drug spending is \$103 billion. Calculated from Office of the Actuary, Health Care Financing Administration, "National Health Expenditures and Selected Economic Indicators, Levels and Average Annual Percent Change: Selected Calendar Years 1970-2008," http://www.hcfa.gov/stats/NHE-Proj/proj1998/tables/table1.htm HCFA estimates total U.S. health care spending at \$1,228.5 billion for 1999.

⁴⁴ Some share—probably a small share—of the rise in retail drug spending reflects the steady shift of health care from inpatient to outpatient settings. The cost of drugs administered to inpatients is considered a cost of hospital care, not of prescription drugs. The prescription drug spending tallied in the federal data reported in this paragraph include only medications dispensed through retail outlets like pharmacies or mail order services.

⁴⁵ Calculated from Office of the Actuary, Health Care Financing Administration, "National Health Expenditures and Selected Economic Indicators, Levels and Average Annual Percent Change: Selected Calendar Years 1970-2008," http://www.hcfa.gov/stats/NHE-Proj/proj1998/tables/table1.htm

⁴⁶ Organization for Economic Cooperation and Development, *OECD Health Data, 1998*, from www.phrma.org/publications/industry/profile99.

⁴⁷ Prescription Drug Pricing in the United States: Drug Companies Profit at the Expense of Older Americans, Minority Staff Report, Committee on Government Reform and Oversight, U.S. House of Representatives, 20 October 1998, pp. 6-7.

⁴⁸ IMS, "Five Year Forecast of the Global Pharmaceutical Markets: Forecast Growth – North America, Europe, and South East Asia," *Global Pharmaceutical Market Forecasts*, www.ims-global.com/insight/ report/global/; Patricia Danzon, "The Uses and Abuses of International Price Comparisons," in Robert B. Helms, ed., *Competitive Strategies in the Pharmaceutical Industry*, Washington: American Enterprise Institute Press, 1996,

chapter 5, pp. 85-106; U.S. General Accounting Office, *Prescription Drugs: Companies Typically Charge More in the United States than in Canada,* Washington: The Office, September 1992, GAO/HRD-92-110; U.S. General Accounting Office, *Prescription Drugs: Companies Typically Charge More in the United States than in the United Kingdom,* Washington: The Office, January 1994, GAO/HEHS-94-29; U.S. General Accounting Office, *Prescription Drugs: Spending Controls in Four European Countries,* Washington: The Office, May 1994, GAO/HEHS-94-30; U.S. General Accounting Office, *German Health Reforms: Changes Result in Lower Health Costs in 1993,* Washington: The Office, December 1994, GAO/HEHS-95-27; Alicia Ault, "Call for Tightening of US Drug Price Controls," *The Lancet,* Vol. 352 (25 July 1998), p. 299; and Larry D. Sasich, E. Fuller Torrey, and Sidney M. Wolfe, *International Comparisons of Prices for Antidepressant and Antipsychotic Drugs,* Washington: Public Citizen, 15 July 1998, www.publiccitizen.org/public citizen/hrg; Ronald F. White and Sean Fraley, "Imperfect Competition, Price-fairness, and the Pharmaceutical Industry, *The Online Journal of Ethics,* May 1999, www.depaul.edu/ethics/icpfpi/html.

⁴⁹ For example, when Germany in 1989 adopted legislation setting strict limits or "reference prices" for categories of drugs, the industry cooperated promptly. As reported by the *Philadelphia Inquirer*, "'The response of the drug companies was spectacular,' said an economist in Germany's Ministry of Health. 'They even sent sales representatives out on weekends to tell doctors that the prices [of their drugs] would be coming down.' Prices fell an average of 20 percent in the first category of drugs to be indexed." Donald Drake and Marian Uhlman, *Making Medicine, Making Money*, Kansas City: Universal Press Syndicate, Andrews and McMeel, 1993, p. 91.

⁵⁰ See PhRMA, *Pharmaceutical Industry Profile, 1999*, <u>www.phrma.org/publications/industry/profile99</u>, especially chapters 1-4.

⁵¹ Source: Organization for Economic Cooperation and Development, *OECD Health Data, 1996 edition*, Paris: OECD (c.d.) Percentages are means are for all years, 1990 through 1994, for which data were available.

⁵² Health expenditure data for 1995 from OECD Health Data 97. For share of company-financed 1995 R&D by country, see "U.S. Companies Are Doing More Than a Third Of The World's Pharmaceutical R&D," PhRMA, Aug. 1997, http://www.phrma.org/facts/phfacts/8 97a.html.

⁵³ Stephen W. Schondelmeyer, testimony before the Vermont Legislative Health Access Oversight Committee, State House, Montpelier, 21 June 1999.

⁵⁴ "IMS Says Spending More on Rx Could Mean Less Total Health Costs," IMS Press Release, 31 March 1998, http://ims-america.com/communications/pr_LessHealthCost.
httm; Louis Lasagna, "Rx: A Heftier Share for Prescription Drugs: Giving Medicine More of the Health Care Pie Could Cut Costs and Aid Patients," *Boston Sunday Globe* Focus, 29 November 1998. The Clinton administration seems to embrace this hope, wrote Robert Pear, citing "confidential White House documents". See Robert Pear, "Clinton Will Seek a Medicare Change on Drug Coverage," *New York Times*, 8 June 1999.

⁵⁵ Preventing heart attacks would allow many of us to live more years in good health. But whether this would be associated with long-run savings or with long-term cost

increases would depend on the types of problems that sickened or killed us in place of the prevented heart attacks, and the costs of treating them compared with the costs of treating heart attacks. For example, if more of us died of cancer, which required costly treatments, total spending on health care might increase. If more of us died of general frailty and debility after years in a nursing home, total spending on health care would probably increase.

- ⁵⁶Emphasis added. U.S. General Accounting Office, *Prescription Drugs: Spending Controls in Four European Countries*, Washington: GAO, May 1994, GAO/HEHS-94-30, pp. 4-5, 8. On the share of new drugs developed in those four countries, GAO (p. 16, note 2) cites Heinz Redwood, *Price Regulation and Pharmaceutical Research: The Limits of Co-Existence*, Suffolk, England: Oldwicks Press Limited, 1993, p. 22.
- ⁵⁷ See John Hutton, et al., "The Pharmaceutical Industry and Health Reform: Lessons from Europe," *Health Care Financing Review*, Summer 1994, p. 103-4.
- ⁵⁸U.S. General Accounting Office, *Prescription Drugs: Spending Controls in Four European Countries*, Washington: GAO, May 1994, GAO/HEHS-94-30, pp. 39.
- ⁵⁹ This point was made as early as the 1960s, by a drug industry executive. See testimony by Seymour Blackman, executive secretary of Premo Pharmaceutical Laboratories, cited in Estes Kefauver, *In a Few Hands: Monopoly Power in American*, New York: Pantheon, 1965, pp. 16-17.
- ⁶⁰ "1999 Fortune 500," <u>www.pathfinder.com/fortune/fortune500/medians9.html</u>. In recent years, the "*Fortune* 500" actually refers to 1,000 firms in *Fortune*'s measures of industry medians.
- ⁶¹ The 1940s are excluded.
- ⁶² Estes Kefauver, *In a Few Hands: Monopoly Power in America*, New York: Pantheon, 1965, pp. 40-41.
- ⁶³ Estes Kefauver, *In a Few Hands: Monopoly Power in America,* New York: Pantheon, 1965, p. 41.
- ⁶⁴ We report data for 27 years between 1970 and 1998. Data are missing for 1982 and 1983 only. See *Fortune* 500 listings, in April issue of *Fortune* magazine. Each year's issue has the previous year's data.
- ⁶⁵ Cited in Donald Drake and Marian Uhlman, *Making Medicine, Making Money,* Kansas City: Universal Press Syndicate, Andrews and McMeel, 1993, pp. 5, 7 (originally published in *Philadelphia Inquirer*).
- ⁶⁶ See Michael Lasalandra and Jennifer Heldt Powell, "Proposal Calls for State to Negotiate Prescription Prices," *Boston Herald*, 8 June 1999.
- ⁶⁷ Graef Crystal, "The Flap over HMO/Healthcare CEO Pay Premiums," *The Crystal Report*, 11 December 1999.

We converted spending in national currencies into U.S. dollars using the OECD's 1998 purchasing power parities, the most current available. We used 1998 purchasing power parities of 1.16 for Canada and 0.56 for the U.K. (source for PPPs: Organization for Economic Cooperation and Development, http://www.oecd.org/std/ppps.htm.)

⁶⁸ "Corporate America's Most Powerful People: Industry Listings – Health Care Products," *Forbes*, 17 May 1999, www.forbes.com/tool/toolbox/CEO/asp/indindex.

⁶⁹ Donald Drake and Marian Uhlman, *Making Medicine, Making Money,* Kansas City: Universal Press Syndicate, Andrews and McMeel, 1993, p. 15 (originally published in *Philadelphia Inquirer*).

⁷⁰ U.S. Congress, Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks, and Rewards,* OTA H-522, Washington: Government Printing Office, February 1993, pp. 1, 24, 104.

⁷¹ "Do We Pay Too Much for Prescriptions?" *Consumer Reports*, October 1993, p. 671.

⁷² See also Ronald F. White and Sean Fraley, "Imperfect Competition, Price-fairness, and the Pharmaceutical Industry, *The Online Journal of Ethics*, May 1999, www.depaul.edu/ethics/icpfpi/html, citing "Wasted Health Care Dollars, *Consumer Reports*, Vol. 57, No. 7 (July 1992), p. 445.

⁷³ We have not been able to compile accurate data on different nations' public support for prescription drug research alone. Taken in national currencies, in the United States, the National Institutes of Health total budget in FY 1999 was \$15.6 billion. In Canada, medical research "from a variety of sources" was \$800 million (Canadian) in FY 1999. In the United Kingdom, total National Health Service research in FY 1998 was about 400 million pounds, including some health policy research. Medical Research Council funds were an additional 289 million pounds. Sources: Terry Herron, Chief, Program Budget Branch, Office of the Director, National Institutes of Health, 14 June 1999; Michael Stinsen, National Research Council of Canada, 15 June 1999; Whitakers, 1998; and Department of Health (U.K.), "NHS Research", http://www.dti.gov.uk/ost/SETstats98/.

⁷⁴ Top ten U.S. pharmaceutical companies as ranked by sales in 1998. See Maura Kealey, Public Citizen's Congress Watch, testimony before the House Judiciary Subcommittee on Courts and Intellectual Property, 1 July 1999, http://www.citizen.org/congress/drugs/hr1598testimony.html

⁷⁵ Fortune 500 Industry Snapshot, http://www.pathfinder.com/fortune/fortune500/ind21.html.

⁷⁶ Merck Co., Inc. 1997 Annual Report and Pfizer, Inc., 1997 Annual Report.

⁷⁷ Stephen W. Schondelmeyer, testimony before the Vermont Legislative Health Access Oversight Committee, State House, Montpelier, 21 June 1999.

⁷⁸Staff report of the Special Committee on Aging, U.S. Senate, *The Drug Manufacturing Industry: A Prescription for Profits*, U.S. Government Publications Office, September 1991, Serial No. 102F, pp. 7-31, reprinted in Nancy F. McKenzie, ed., *Beyond Crisis:*

Confronting Health Care in the United States, a Health/PAC Book, Boston: Penguin Books USA, 1994, pp. 354, 356. The Committee also noted that some drug makers "disguise postmarketing studies as research studies, and use these studies to promote unapproved uses of their drugs to physicians." (p. 356)

⁷⁹Estimates for 1991 are from *Forbes* magazine, 15 April 1991, based on data provided by the Pharmaceutical Manufacturers Association. (As cited in Staff report of the Special Committee on Aging, U.S. Senate, *The Drug Manufacturing Industry: A Prescription for Profits*, U.S. Government Publications Office, September 1991, Serial No. 102F, pp. 7-31, reprinted in Nancy F. McKenzie, ed., *Beyond Crisis: Confronting Health Care in the United States*, a Health/PAC Book, Boston: Penguin Books USA, 1994, pp. 352, 354-5.)

⁸⁰AAMP analysis of manufacturers' data reported in *Med. Ad. News*, September 1994, as cited by National Association of Chain Drugstores.

⁸¹ See, for example, Estes Kefauver, *In a Few Hands: Monopoly Power in America*, New York: Pantheon, 1965, pp. 23-25.

⁸² Recently, for example, see Stephen W. Schondelmeyer, testimony before the Vermont Legislative Health Access Oversight Committee, State House, Montpelier, 21 June 1999.

⁸³ Public Citizen, "Stop Claritin's Billion Dollar Patent Extension Grab!" 20 May 1999, www.citizen.org/congress/drugs/steopclaritin.htm.

⁸⁴ Cost estimate from study by Stephen Schondelmeyer of the University of Minnesota, cited in "Pocketbook Politics: How Special-Interest Money Hurts the American Consumer," Common Cause, 24 February 1998. See also Michael F. Cannon, "Suppressing Generic Drugs Fleeces Consumers (and Lets the FDA off the Hook)," Citizens for a Sound Economy Foundation. 25 February 1999.

⁸⁵See William L. Fritz, "Controlling Expensive Drug Utilization," *Dynamics in Health Care*, vol. 4, no. 1, Nov. 1992, p. 8.

⁸⁶J.D. Kleinke, "Expensive Drugs Lower Health Care Costs," *Wall Street Journal*, 16 February 1994.

⁸⁷Dr. Charles G. Moertel, as cited by the Associated Press, May 20, 1992, and United Paperworkers International Union Special Projects, October 1992. See also Donald Drake and Marian Uhlman, *Making Medicine, Making Money*, Kansas City: Universal Press Syndicate, Andrews and McMeel, 1993, pp. 69-70.

⁸⁸Sanford Bernstein drug analysts Marc Mayer and John Borzilleri, as cited in Robert Lenzner, "Drug firms in the eye of a storm," *Boston Globe*, 27 February 1992.

⁸⁹Staff report of the Special Committee on Aging, U.S. Senate, *The Drug Manufacturing Industry: A Prescription for Profits*, U.S. Government Publications Office, September 1991, Serial No. 102F, pp. 7-31, reprinted in Nancy F. McKenzie, ed., *Beyond Crisis: Confronting Health Care in the United States*, a Health/PAC Book, Boston: Penguin Books USA, 1994, p. 364. The Families USA Foundation study, *Worthless Promises:*

Drug Companies Keep Boosting Prices (March 1995), reports that the manufacturer increased the recommended wholesale price for Premarin eight separate times between 1989 and 1994.

⁹⁰ Jamie Love, "Companies Loot Public Funding for Drug Research," *Public Citizen*, Fall 1994, p. 26.

⁹¹Seymour Zelmanoff, letter to the editor, *Nation*, 27 February 1995, p. 258; and personal communication, 14 February 1993. Stephen W. Schondelmeyer, "Competition and Pricing Issues in the Pharmaceutical Market," Minneapolis: PRIME Institute, August 1994, p. 1. Data from *Drug Topics* cited in Health Economics Program, Minnesota Department of Health, *Prescription Drug Study: A Report to the Minnesota Legislature on the Prescription Drug Market*, April 1994, p. 22. The Minnesota report describes, for example, the purchase by Hoechst Celanese of a controlling interest in generic maker Copley Pharmaceuticals, "largely predicated on Hoechst selling Copley the ingredients to produce generic equivalents of its two brand-name drugs when they come off patent -- Diabeta and Trental," thus acquiring an edge over other potential generic makers, which would take longer to get their products on the market. Zelmanoff notes that as patents expire on a substantial number of the most widely-used prescription drugs in the next few years, control of generic drug pricing will become increasingly crucial.

⁹²Jamie Love, "Companies Loot Public Funding for Drug Research," *Public Citizen*, Fall 1994, p. 26. U.S. Congress, Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards*, OTA H-522 (Washington, D.C.: U.S. Government Printing Office, February 1993), p. 234.

⁹³Warren E. Leary, "U.S. Gives Up Right to Control Drug Prices," *New York Times*, 12 April 1995.

⁹⁴ World Bank, World Development Indicators, 1998 (CD).

⁹⁵ Housing and Economic Statistics Division, U.S. Bureau of the Census, unpublished data from the 1970, 1980, and 1990 decennial censuses.

⁹⁶ Housing and Economic Statistics Division, U.S. Bureau of the Census, unpublished data from the 1990 decennial census.

⁹⁷ Organization for Economic Cooperation and Development, *OECD Health Data, 1998*. In 1996, U.S. health spending per person was \$3,898; the average for 18 other OECD nations was \$1,742—a difference of 223.8 percent.

⁹⁸ Still, as drug costs continue to rise, even Medicare faces greater exposure to the risk of financing medications. And proposed Medicare payment reforms could be compromised or made more complicated by prescription drug cost problems. For example, as Medicare moves toward prospective payment for outpatient services, outpatient treatment of cancer might be affected by prescription drug costs. See Ann Saphir, "Cancer-care Groups Challenge PPS Plan," *Modern Healthcare, 31 May 1999, p. 30.*

- ¹⁰¹ Pharmaceutical Research and Manufacturers of America, "International Price Comparisons," Industry Issue Brief, 1994, cited in Alan Sager and Deborah Socolar, "Do Rx Drugs Cost Too Much? The Market Needs a Peace Treaty," *Business and Health*, Vol. 15, No. 10 (October 1997), pp. 51-53.
- ¹⁰² Alan F. Holmer, "Another Prescription Plan," *Boston Globe*, letter to the editor, 11 February 1999.
- ¹⁰³ "Price Controls Are Bad Medicine," PhRMA News Release, 3 May 1999, www.phrma.org/news/5-3-99.html.
- ¹⁰⁴ Carl B. Feldbaum, "Price Controls Could Be Lethal to Biotech," Business op-ed, *Boston Globe*, 20 April 1999.
- ¹⁰⁵ Alan F. Holmer, "Another Prescription Plan," *Boston Globe*, letter to the editor, 11 February 1999.
- ¹⁰⁶ Pharmaceutical Research and Manufacturers of America, "The Market Is Working," PhRMA Policy Papers, www.phrma.org/issues/market.html.
- ¹⁰⁷ "Study: More Than a Million Have No Prescription Drug Coverage," Associated Press, 7 June 1999.
- ¹⁰⁸ Rebecca Derby, Personal Communication, 24 June 1999.
- ¹⁰⁹ Remarks by Bruce Bullen, Commissioner, Division of Medical Assistance, at Massachusetts Health Council, 5 March 1999.
- ¹¹⁰ Source: National Association of Chain Drug Stores, "The Facts about Prescription Drug Pricing," Alexandria, Virginia: NACDS, 1999 (unpublished draft), 3rd quarter 1998, chain drugs stores only.
- ¹¹¹ Prescription drug manufacturers have been accused of substantial anti-competitive practices. See Estes Kefauver, *In a Few Hands: Monopoly Power in America*, New York: Pantheon, 1965. Prescription drug manufacturers often make vitamins as well; serious anti-trust problems have emerged here as well. Roche and BASF have paid fines of \$725 million to escape U.S. price-fixing charges for vitamins. See "Swiss Investigate Vitamin Cartel," *The Lancet*, Vol. 354 (3 July 1999), p. 55.
- ¹¹² Pharmaceutical Research and Manufacturers of America, "The Market Is Working," PhRMA Policy Papers, www.phrma.org/issues/market.html .
- 113 As noted elsewhere, we have used an estimated price elasticity of demand of -0.33. In a recent analysis by Merrill Lynch, the calculations appear to rest on a substantially

⁹⁹ William A. Glaser, "Paying the Hospital: Foreign Lessons for the United States," *Health Care Financing Review*, Vol. 4, No. 4 (Summer 1983), pp. 99-110.

¹⁰⁰ See, for example, Robert Pear, "Democrats Seek Medicare Coverage for Prescription Drugs," *New York Times*, 21 April 1999.

higher price elasticity of demand. Thus, a 40 percent drug price cut for Medicare beneficiaries is expected by Merrill Lynch to have a surprisingly small effect on manufacturers' total revenues—something between a reduction of 3.3 percent and a rise of 1.3 percent. Note that the Merrill Lynch calculations, as they analyze the effect of price cuts on drug company revenues, are addressing the prospective change in total company revenue, not simply the change in domestic pharmaceutical revenue. (Merrill Lynch, *Pharmaceuticals: A Medicare Drug Benefit May Not Be So Bad,* In-depth report on United States Pharmaceuticals, 23 June 1999.)

- We assume (as discussed elsewhere) that retailers and wholesalers' costs average 26 percent—and manufacturers' costs 74 percent—of the retail cost of prescription drugs. Just two to three percent of the total is for wholesalers' own operations. So the average dispensing cost of prescriptions generally is nearly one-fourth of their retail price. The dispensing cost assumed here is just half of that, about one-eighth the average retail price.
- ¹¹⁵ Some communities may, however, have lost a substantial share of their pharmacies. See, for example, Access and Affordability Monitoring Project, *Pharmacy Closings in Massachusetts*, *1980-1995*, Boston: The Project, 15 May 1997.
- ¹¹⁶ Pharmaceutical Research and Manufacturers of America, "The Market Is Working," PhRMA Policy Papers, www.phrma.org/issues/market.html. See pages 5-6, Saving Money on Prescription Drugs.
- ¹¹⁷ Art Nadler, "HMOs' Order to Divide Tablets Concerns Doctors," *Las Vegas Sun*, 14 June 1999.
- ¹¹⁸ See, for example, Estes Kefauver, *In a Few Hands: Monopoly Power in America,* New York: Pantheon, 1965, pp. 11 ff.

- ¹²⁰ Pharmaceutical Research and Manufacturers of America, "Competition from Generic Drugs," in *Pharmaceutical Industry Profile, 1999*, www.phrma.org/publications/industry/profile99/chapt5.html, chapter 5.
- ¹²¹ Thomas Burton, "Bested Interests: Why Generic Drugs Often Can't Compete Against Brand Names," *Wall Street Journal*, 18 November 1998.
- ¹²² Campaign for Fair Pharmaceutical Competition, "How the Brand Drug Industry Blocks Access to More Affordable Generic Drugs, Washington: The Campaign, 1999.
- ¹²³ Thomas Burton, "Bested Interests: Why Generic Drugs Often Can't Compete Against Brand Names," *Wall Street Journal*, 18 November 1998.
- ¹²⁴ U.S. Congress, Office of Technology Assessment, *Benefit Design in Health Care Reform: Background Paper Patient Cost-Sharing*, OTA-BP-H-112, Washington, DC: U.S. Government Printing Office, September 1993, p. 4. Another very useful discussion of many problems with requiring patient cost-sharing is M. Edith Rasell, "Cost Sharing in

¹¹⁹ Such as tablets.

Health Insurance – A Reexamination," *New England Journal of Medicine*, Vol. 332, No. 17 (27 April 1995).

- ¹²⁵ For medical services, cost-sharing plans in the experiment involved coinsurance estimated at 21 percent, on average, with income-linked out-of-pocket caps. See, for example, Kathleen Lohr et al., "Use of medical care in the Rand Health Insurance Experiment: diagnosis and service-specific analyses in a randomized controlled trial," *Medical Care* (September 1986), Supplement, p. S79.
- ¹²⁶ Kathleen Lohr et al., "Use of medical care in the Rand Health Insurance Experiment: diagnosis and service-specific analyses in a randomized controlled trial," *Medical Care* (September 1986), Supplement, p. S72, S 78.
- ¹²⁷ C.E. Reeder and Arthur A. Nelson, "The Differential Impact of Copayment on Drug Use in a Medicaid Population," *Inquiry*, Vol. 22 (Winter 1985), pp. 396-403. Brian L. Harris et al., "The Effect of Drug Co-Payments on Utilization and Cost of Pharmaceuticals in a Health Maintenance Organization," *Medical Care*, Vol. 28, No. 10 (October 1990), pp. 907-917. In that study, a \$3 co-payment was associated with a 13 percent reduction in prescriptions filled for essential drugs, and 19 percent for discretionary prescriptions.
- ¹²⁸ Kathleen Lohr et al., "Use of medical care in the Rand Health Insurance Experiment: diagnosis and service-specific analyses in a randomized controlled trial," *Medical Care* (September 1986), Supplement, p. S74-5; see especially Table 8.2.
- ¹²⁹ Kathleen Lohr et al., "Use of medical care in the Rand Health Insurance Experiment: diagnosis and service-specific analyses in a randomized controlled trial," *Medical Care* (September 1986), Supplement, p. S74.
- ¹³⁰ We have not obtained confirmatory evidence of this, but it is certainly widely believed among retailers. As of the mid-1990s, dispensing fees and net profits for pharmacists nationally had held steady or declined for over two decades, a University of Minnesota researcher found. See Stephen W. Schondelmeyer, "Pharmaceuticals and the Dynamics of Health Care Reform," *Dynamics in Health Care*, vol. 4, no. 1, Nov. 1992, p. 14. Similarly, see Health Economics Program, Division of Health Care Delivery Systems, Minnesota Department of Health, *Prescription Drug Study: A Report to the Minnesota Legislature on the Prescription Drug Market*, Minneapolis: The Department, April 1994, pp. 10-11.
- ¹³¹ Michael Lasalandra, "Druggist Probe Uncovers Millions of Errors," *Boston Herald*, 10 February 1999. See also, Richard A. Knox, "Prescription Errors Tied to Lack of Advice: Pharmacists Skirting Law, Mass. Study Finds," *Boston Globe*, 10 February 1999; and "Rx for Drug Stores," *Boston Business Journal*, editorial, 12 February 1999.

¹³² Source: National Association of Boards of Pharmacy.

¹³³ This has been re-introduced as the Prescription Drug Fairness for Seniors Act, H.R. 664, 106th Congress, First Session, 10 February 1999. Sen. Edward M. Kennedy and others filed a parallel Senate bill, S. 731, in May 1999.

¹³⁴ H.R. 664, section 3(a)(1) and –(2).

¹³⁵ Prescription Drug Fairness for Seniors Act of 1998, Summary.

¹³⁶ Prescription Drug Pricing in the United States: Drug Companies Profit at the Expense of Older Americans, Washington: Minority Staff Report, Committee on Government Reform and Oversight, U.S. House of Representatives, updated 20 October 1998. See also Alissa J. Rubin, "Elderly Paying Double for Prescriptions," Los Angeles Times, 26 September 1998.

¹³⁷ Merrill Lynch, *Pharmaceuticals: A Medicare Drug Benefit May Not Be So Bad*, Indepth report on United States Pharmaceuticals, 23 June 1999. The Merrill Lynch calculations analyze the effects of price cuts on drug company total pharmaceutical revenues, rather than simply the anticipated change in domestic revenues. They first examine the direct impact of the 40 percent discount on revenues, and then consider the impact of price elasticity, with the possible rise in volume.

¹³⁸ "Indian Tribe Builds Drug Business," Associated Press, 18 June 1999.

¹³⁹ The bill is SB 393, Affordable Prescriptions for Seniors.

¹⁴⁰ House budget amendment no. 930, Rep. William Straus, lead sponsor. The discounts from posted retail price might range from 12 – 15 percent in retail pharmacies to 20 – 50 percent by mail order. See Richard A. Knox, "Disabled Adults May Get State Aid,' *Boston Globe*, 9 May 1999. Rep. Straus noted that "…it makes no sense to just increase access to the senior pharmacy-assistance program without addressing the problem of prices. 'We will simply be having the taxpayers subsidize an overly expensive program,' Mr. Straus says.'" See Carol Gentry, "Drug Firms Combat Price Curbs," *Wall Street Journal*, 30 June 1999.

¹⁴¹ If a state did this, Medicaid patients would have to be excluded unless the state won prices at least as low as those required under federal law.

¹⁴² http://www.mmd.admin.state.mn.us/mmcap.htm.

¹⁴³ H. 2886, "An Act to Reduce Outpatient Prescription Drug Costs and to Expand Coverage," Rep. Patricia Jehlen, lead sponsor, was recently sent to the Massachusetts House Committee on Ways and Means. A similar bill was filed in 1995; it garnered broad support.

¹⁴⁴ H. 365 (1999), "An Act Relating to the Vermont Prescription Drug Pricing and Consumer Protection Program." See also Dennis Cauchon, "Vt. ahead in trying to control drug costs, Legislators frustrated that prices in Canada are one-third less," *USA Today*, 20 July 1999, p. 8A.

¹⁴⁵ Alan Sager, "Affordable Medications for Vermont," testimony on H. 365, "An Act Relating to the Vermont Prescription Drug Pricing and Consumer Protection Program," by telephone before the House Health and Welfare Committee, State of Vermont, 28 April 1999.

¹⁴⁶ We begin with the estimated \$2.5 billion in Massachusetts retail prescription drug spending. We remove the 26 percent that goes for retail and wholesalers' cost as this would not be subject to the rebate. We take 17 percent of the remainder—the unweighted average of the brand name and generic discount. The result is \$314.5 million. In reality, a small share of this would go to program administration, but that would be more than offset by the multiplier effect. That is, medications bought with the rebated money would themselves be subject to the rebate.

¹⁴⁷ We have seen estimates of the price elasticity of demand for prescription drugs ranging from -0.10 to -0.64. In these calculations, we use -0.33 as one estimate close to the mid-point in this range. See, for example, Mandy Ryan and Stephen Birch, "Charging for Health Care: Evidence on the Utilisation of NHS Prescribed Drugs," *Social Science and Medicine*, Vol. 33, No. 6 (1991), pp. 681-687; B. O'Brien, "The Effect of Patient Charges on the Utilisation of Prescription Medicines," *Journal of Health Economics*, Vol. 8, No. 1 (March 1989), pp. 109-132; R.J. Lavers, "Prescription Charges, the Demand for Prescriptions, and Morbidity," *Applied Economics*, Vol. 21 (1989), pp. 1043-1052.

¹⁴⁸ They save \$24 million by buying for \$110 million what undiscounted would have cost \$134 million, if prices had remained 18 percent higher.

¹⁴⁹ Again, this assumes a price elasticity of demand of –0.33. The Merrill Lynch study cited earlier appears to assume price cuts will yield much larger volume increases, and thus it suggests a much smaller revenue loss, and possibly even a minor revenue gain from a 40 percent price cut.

¹⁵⁰ This might be justified by a desire to control the consumption of alcohol.

¹⁵¹ The drug manufacturers sometimes try to deny that this is true of Canada, and they assert that they deliberately charge lower prices in Mexico because incomes are lower there.

¹⁵² "Sanders Introduces `Free Trade' Bill for Prescription Drugs," Press Release, www.house.gov/bernie/press/1999/05-20-99.html. The bill is H.R. 1885; the Senate counterpart is S. 1191, sponsored by Senators Dorgan, Wellstone, Snowe, and others.

¹⁵³ Alex Pham, "Bill Planned to Allow US Retailers to Import Drugs," *Boston Globe*, 20 May 1999. (The words cited are the reporters.)

¹⁵⁴ www.phrma.org/publications/industry/profile99/chap7.html#parallel.

¹⁵⁵ Pharmaceutical Research and Manufacturers of America, "Prescription Drug Prices and Profits," PhRMA Facts and Figures, p. 5, www.phrma.org/facts/bkgrnder/prices/html.

¹⁵⁶ Fourteen such state programs are described in David Gross and Sharon Bee, *State Pharmacy Assistance Programs*, Washington: American Association of Retired Persons, Public Policy Institute, April 1999.

- National Economic Council, Domestic Policy Council, *The President's Plan to Modernize and Strengthen Medicare for the 21st Century*, http://www.pub.whitehouse.gov/uri-res/12R?urn:pdi://oma.eop.gov.us/1999/7/6/17.text.2. See also Robin Toner, "Prescription Drug Coverage Dominates Fight Brewing on Medicare Overhaul," *New York Times*, 16 June 1999; and Robert Pear, "Clinton Will Seek a Medicare Change on Drug Coverage," *New York Times*, 8 June 1999.
- ¹⁶¹ Associated Press, "Drug Stocks Soar in Light of Medicare Proposal," *Boston Globe* 30 June 1999.
- ¹⁶² Carey Goldberg, "Massachusetts Chief Joins Effort on Drug Insurance for Elderly," *New York Times*, 8 July 1999; Kristin Vaughan, "Cellucci Outlines Drug Coverage for Seniors," *Boston Globe*, 7 July 1999.
- ¹⁶³ Arthur Mazer, "Cellucci's Prescription Drug Plan is No Cure," letter to the editor, *Boston Globe*, 9 July 1999. With most enrollees having to pay \$2,100 themselves in annual premium and deductible, Mazer calculated that, for example, seniors slightly above that threshold— earning \$14,000, for example— "would have to pay 15 percent of their income for drugs before the benefit contributed one cent."
- ¹⁶⁴ Richard A. Knox, "State Eyes Drug Coverage for Elderly," *Boston Globe*, 21 May 1999.
- ¹⁶⁵ Alan Sager and Deborah Socolar, "Flaws in Governor Cellucci's Prescription Drug Plan," *Boston Globe*, 31 May 1999.
- ¹⁶⁶ See, for example, Carol Gentry, "HMO Pays Drug Stores A Flat Fee," *Wall Street Journal*, 18 March 1998; and Alex Pham, "Drug Costs Put Strain on Health Insurors: May Force Change for Managed Care," *Boston Globe*, 18 March 1999.
- ¹⁶⁷ This \$300 million reflects rebates from manufacturers amounting to 20 percent of manufacturers' revenue for brand name drugs and 14 percent for generics. The manufacturers' share is estimated at 74 percent of the \$2.5 billion in projected 1999 Massachusetts retail spending on prescription drugs. See Alan Sager and Deborah Socolar, "A Fairer Prescription Drug Plan," *Boston Globe* op-ed, 26 January 1999; Carol Gentry, "Bay State May Negotiate Price of Pharmaceuticals," *Wall Street Journal*, New England Edition, 9 December 1998.

¹⁵⁷ Michael E. Gluck, *A Medicare Prescription Drug Benefit*, National Academy of Social Insurance, Medicare Brief No. 1, April 1999, www.nasi.org/Medicare/medbr1.htm.

¹⁵⁸ The bills are S 841/HR 1495, "The Access to Rx Medications in Medicare Act," introduced by Sen. Kennedy and Rep. Stark. See also Melissa B. Robinson, "Democrats Unveil Medicare Drug Plan," Associated Press, 21 April 1999.

¹⁵⁹ Robert Pear, "Democrats Seek Medicare Coverage for Prescription Drugs," *New York Times*, 21 April 1999.

¹⁶⁸ This assumes that the current division of the retail dollar persists.

That is because the fixed costs of basic research, testing, setting up the manufacturing plants, and marketing are so high. The true incremental or marginal costs of making more medications are therefore very low, except for unusual products that employ costly raw materials, or that require costly fabrication processes. (Often, apparently, the large drug manufacturers simply purchase drugs in bulk form, very inexpensively, from chemical companies that makes them; the drug companies then put the medication into pill form or capsules.) In 1997, as shown earlier, Merck and Pfizer reported in their annual reports that materials and production consumed 34.0 percent of their total revenue. If the manufacturers' share of retail revenue remains at 74 percent, then the 34 percent of manufacturers' revenue equals 25.2 percent. If the average cost of manufacturing is 25 percent of retail spending, we are comfortable with a marginal cost equal to one-fifth of the average.

Since drug makers treat all such information as proprietary, those concerned about this issue only have ready access to scattered examples that suggest specific drugs' costs. In some cases, the likely gap between retail price and actual marginal cost of production may be approximated (or hinted at) by noting the gap between prices that drug manufacturers charge different customers for a given product. A few examples presented here suggest that it is reasonable to estimate marginal cost at five percent of retail:

The standard retail price that patients paid out-of-pocket for Knoll Pharmaceuticals' Synthroid recently was 1446 percent of (or more than 14 times) the price charged to the company's "most favored customers"—so the lower price was just *seven percent* of what seniors paid. (Public Citizen, "Why Medicare Doesn't Cover Prescription Drugs," http://www.citizen.org/congress/drugs/nosecretitsscandal.htm)

As discussed elsewhere in the text, Johnson & Johnson was charging human patients nearly \$1500 for a year's supply of levamisole, but if the same amount of the same drug were purchased from a competitor for treating sheep, the price would be just \$14 and change. So animals received the drug at *less than one percent* of the price charged human patients. (Dr. Charles G. Moertel, as cited by the Associated Press, May 20, 1992, and United Paperworkers International Union Special Projects, October 1992.)

As reported by the Consumer Project on Technology and others, Bristol-Myers set the wholesale price at \$4.87 per milligram for Taxol when it went on the market in 1992. But during the just-previous clinical trials, Bristol-Myers had provided Taxol purchased from a supplier, Hauser Chemicals, at 25 cents per milligram—or *just over five percent* of the price Bristol-Myers later charged. (For a recent description of this case, see Ken Silverstein, "Millions for Viagra, Pennies for Diseases of the Poor," and its companion article, "Public \$, Private Gain," *The Nation*, 19 July 1999, pp. 13-19, http://www.thenation.com/issue/990719/0719silverstein.shtml.)

(Note that at least two of these cases involve only manufacturers' prices; since the retail price would be even higher, the actual production cost as a share of retail price would be substantially smaller than the percentage indicated here.)

¹⁷⁰ Certain minor financial factors are not reflected in these estimates. The amount of money available in the rebate-financed trust fund to buy medications would be reduced

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slightly by the cost of administering the program. But these costs are expected to be very low. Still, they would reduce slightly the share of the rebated sums that would be returned to the manufacturers. But this reduction would be offset if the trust fund were able to negotiate a schedule of payments to pharmacies that reduced the retailers/wholesaler share of the retail prescription drug dollar below the 26 percent average that currently prevails. The pharmacies' marginal costs should be well below their average costs.

- Again, this assumes a price elasticity of demand of –0.33. The Merrill Lynch study cited elsewhere suggests a much smaller revenue loss, and possibly even a minor revenue gain from a 40 percent price cut.
- ¹⁷² See Michael Lasalandra and Jennifer Heldt Powell, "Proposal Calls for State to Negotiate Prescription Prices," *Boston Herald*, 8 June 1999.
- ¹⁷³ Pharmaceuticals Industry Snapshot, *Fortune* Magazine, www.pathfinder.com/fortune/fortune500/ind21.html.
- ¹⁷⁴ "1999 *Fortune* 500 Industry Medians," Return on Revenue, www.pathfinder.com/fortune/fortune500/medians7.html.
- ¹⁷⁵ "Corporate America's Most Powerful People: Industry Listings Health Care Products," *Forbes*, 17 May 1999, www.forbes.com/tool/toolbox/CEO/asp/indindex.
- ¹⁷⁶ IMS Health, News Release, 7 June 1999, <u>www.imshealth.com/html/</u>news/arc/06_07_1999_211.htm.
- ¹⁷⁷ See, for example, Eric P. Cohen, "Direct-to-the-Public Advertisement of Prescription Drugs," *New England Journal of Medicine*, Vol. 318, No. 6 (11 February 1998), pp. 373-376. More generally, see Sarah Jones, "Bill Seeks Limits to Healthcare Ads," *Adweek*, 8 March 1998.
- ¹⁷⁸ Public Citizen, "Who's Pulling the Strings in Washington?" http://www.citizen/org/congress/drugs/strings.htm
- Robert Pear, "Drug Makers Fault the Details of Clinton Medicare Proposal," *New York Times*, 16 July 1999; Elyse Tanouye and Laurie McGinley, "Drug Firms Are Seeking Strategy That Won't Spark Public Backlash," *Wall Street Journal*, 14 July 1999.

 180 The Tenth Annual Human Development Report just released by the United Nations stated, "Corporations define research agendas. . . . Money talks, not need. Cosmetic drugs...come higher on the priority list than...a vaccine against malaria." The report called for a new "global architecture" to facilitate addressing the problems of developing nations. As cited in R.C. Longworth, "A `Grotesque' Gap: The Global Economy's Winners and Losers Are So Far Apart That Balancing Efforts Are Needed to Avoid Disaster, According to a New UN Overview," Chicago Tribune, 12 July 1999, http://chicagotribune.com/version1/article/0,1575,SAV-9907120104,00.html

Indeed, an analysis by Doctors Without Borders found that between 1975 and 1997, just one percent of the new medicines marketed by multinational drug makers (13 out of 1,223 drugs) were designed to treat tropical diseases in developing nations. As cited in

Ken Silverstein, "Millions for Viagra, Pennies for Diseases of the Poor: Research Money Goes to Profitable Lifestyle Drugs," *The Nation*, 19 July 1999, pp. 13-19, http://www.thenation.com/issue/990719/0719silverstein.shtml

¹⁸¹ Alan Sager and Deborah Socolar, "Do Rx Drugs Cost Too Much? The Market Needs a Peace Treaty," *Business and Health*, Vol. 15, No. 10 (October 1997), pp. 51-53.

¹⁸² See, for example, the testimony concerning both inappropriate advertising and high advertising and marketing costs in Estes Kefauver, *In a Few Hands: Monopoly Power in America*, New York: Pantheon, 1965, pp. 17-18, 48 ff.